California State Board of Pharmacy
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STATE AND CONSUMER SERVICES AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
GOVERNOR EDMUND G. BROWN JR.

Enforcement Committee Report

Randy Kajioka, PharmD, Chair, Professional Member
Shirley Wheat, Public Member
Tappan Zee, Public Member
Rosalyn Hackworth, Public Member
Amy Gutierrez, PharmD, Professional Member

Report of the Meeting Held March 14, 2013.

a.   **FOR ACTION: Request from Walgreens to Store Prescription Records Older than Five Years Outside of a Licensed Pharmacy**

Attachment 1

Background:

California has requirements that all pharmacy records be readily retrievable in the licensed premises, and open to inspection by the board. These records are generally required to be retained for at least three years.

California law also permits the offsite storage of records if an offsite waiver has been approved by the board.

Request:

Walgreens has requested that because CMS requires storage of records for 10 years, they would like the ability to store records older than five years offsite at a firm that specializes in records storage. The specific is provided as **Attachment 1**.

Discussion and Action by the Committee:

Al Carter, representing Walgreens provided the committee with an overview of the requirements for records retention to comply with the requirements of CMS. Walgreens had requested authorization to store records off site after five years. The records storage is an issue because law specifies which persons have access to records, including pharmacy staff. The offsite storage vendor is not included in those authorized persons, although five years is two years longer than the three-year record retention period required by CA Pharmacy Law.

Mr. Carter provided an overview of the proposed vendor, Iron Mountain, which has multiple locations statewide. He commented that records will be stored on a store by

store basis and will only be accessed by Iron Mountain staff. Mr. Carter indicated that any access to the records will be recorded.

Discussion included mention that Iron Mountain has to respond to a request for records, per the contract, and provide the records within 48 hours. Iron Mountain is already used by some pharmacies with approved offsite-waivers to store records to comply with California's three-year retention requirements.

One concern of the committee was how records would be destroyed after the time period had elapsed or if the pharmacy closes before the three years are elapsed. In response, Mr. Carter stated that the contract specifies that the only authorized storage sites may be used and that if Walgreens fails to pay the vendor, the records would be returned to Walgreens.

Mr. Carter indicated that Walgreens could provide a spreadsheet that includes each pharmacy and the location of the Iron Mountain facility where the records will be stored.

Motion of the Enforcement Committee: Recommend to the board to approve Walgreens request for offsite storage of records older than five years.

Staff note: the board may want to add a provision to the motion to ensure that the board is notified where the records are stored, and to use the process outline in 16 California Code of Regulations section 1707 (Waiver Requirements for Off-Site Records).

b. **FOR DISCUSSION: Walgreens Request to Install an Automated Drug Delivery Device (or Kiosk) in Workplace Centers**

Attachment 2

Background:

Several years ago, the board promulgated a regulation (16 California Code of Regulation section 1713) to allow for the use of automated delivery devices, which are markedly like vending machines, to permit the furnishing of refill medication in specified circumstances. These circumstances include, that the patient must opt in to use the machine, the medication to be refilled through the machine is appropriate. The conditions are listed below in the highlighted segment of section 1713.

1713. Receipt and Delivery of Prescriptions and Prescription Medications Must Be to or From Licensed Pharmacy
(a) Except as otherwise provided in this Division, no licensee shall participate in any arrangement or agreement, whereby prescriptions, or prescription medications, may be left at, picked up from, accepted by, or delivered to any place not licensed as a retail pharmacy.
(b) A licensee may pick up prescriptions at the office or home of the prescriber or pick up or deliver prescriptions or prescription medications at the office of or a residence designated by the patient or at the hospital, institution, medical office or clinic at which the patient

receives health care services. In addition, the Board may, in its sole discretion, waive application of subdivision (a) for good cause shown.

(c) A patient or the patient's agent may deposit a prescription in a secure container that is at the same address as the licensed pharmacy premises. The pharmacy shall be responsible for the security and confidentiality of the prescriptions deposited in the container.

(d) A pharmacy may use an automated delivery device to deliver previously dispensed prescription medications provided:

    (1) Each patient using the device has chosen to use the device and signed a written consent form demonstrating his or her informed consent to do so.

    (2) A pharmacist has determined that each patient using the device meets inclusion criteria for use of the device established by the pharmacy prior to delivery of prescription medication to that patient.

    (3) The device has a means to identify each patient and only release that patient's prescription medications.

    (4) The pharmacy does not use the device to deliver previously dispensed prescription medications to any patient if a pharmacist determines that such patient requires counseling as set forth in section 1707.2(a)(2).

    (5) The pharmacy provides an immediate consultation with a pharmacist, either in-person or via telephone, upon the request of a patient.

    (6) The device is located adjacent to the secure pharmacy area.

    (7) The device is secure from access and removal by unauthorized individuals.

    (8) The pharmacy is responsible for the prescription medications stored in the device.

    (9) Any incident involving the device where a complaint, delivery error, or omission has occurred shall be reviewed as part of the pharmacy's quality assurance program mandated by Business and Professions Code section 4125.

    (10) The pharmacy maintains written policies and procedures pertaining to the device as described in subdivision (e).

(e) Any pharmacy making use of an automated delivery device as permitted by subdivision (d) shall maintain, and on an annual basis review, written policies and procedures providing for:

    (1) Maintaining the security of the automated delivery device and the dangerous drugs within the device.

    (2) Determining and applying inclusion criteria regarding which medications are appropriate for placement in the device and for which patients, including when consultation is needed.

    (3) Ensuring that patients are aware that consultation with a pharmacist is available for any prescription medication, including for those delivered via the automated delivery device.

    (4) Describing the assignment of responsibilities to, and training of, pharmacy personnel regarding the maintenance and filing procedures for the automated delivery device.

    (5) Orienting participating patients on use of the automated delivery device, notifying patients when expected prescription medications are not available in the device, and ensuring that patient use of the device does not interfere with delivery of prescription medications.

    (6) Ensuring the delivery of medications to patients in the event the device is disabled or malfunctions.

(f) Written policies and procedures shall be maintained at least three years beyond the last use of an automated delivery device.

(g) For the purposes of this section only, "previously-dispensed prescription medications" are those prescription medications that do not trigger a non-discretionary duty to consult under section 1707.2(b)(1), because they have been previously dispensed to the patient by the pharmacy in the same dosage form, strength, and with the same written directions.

In 2009-10, Pharmacist Consultant Philip Burgess, on behalf of a manufacturer of one of these machines (Asteres), sought an exemption to permit the use of these machines in areas away from adjacent to the licensed pharmacy premises. The board did not approve the request, and requested more information about how and where the kiosks would be used. One concern was that the board considered that it lacked the ability to provide the exemption sought (which would have required a regulation change). There was no further interest pursued by Asteres after the January 2010 meeting. Materials covering some of these discussions are provided in **Attachment 2**.

Committee Discussion and Action:

Walgreens recently requested an opportunity to address the board to seek a waiver of 1713 to permit the use of an automated delivery device in a workplace setting, away from a pharmacy. A copy of this request is provided in **Attachment 2**.

Mr. Carter, representing Walgreens, discussed the request that would allow Walgreens to place kiosks in workplace settings. Mr. Carter advised the committee that the workplace has a clinic on an employee campus that serves a large number of employees.

Mr. Carter provided an overview of the types of services that are provided at the clinic and how Walgreens would provide medication. Mr. Carter highlighted that the kiosk would not be located in the clinic, but would be housed across the street in a separate building. The kiosk would be in a secured building and advised the committee that a patient would have access to a pharmacist via a video link 24 hours a day.

Mr. Carter discussed who will put the medications in the machine and the safety features of the machine including barcoding. Safety features include a log-in and pin or a fingerprint scan and pin number. A camera is also used to take pictures for auditing purposes. Mr. Carter discussed the specifics of the enrollment process. Mr. Carter indicated that no refrigerated items or bulk items would be provided via this kiosk. [A copy of Mr. Carter's PowerPoint presentation is provided at the conclusion as part of the meeting minutes.]

In response to questions Mr. Carter stated that an authorized agent could pick up the prescription since there was a consent process in place, but the authorized agent is limited to just family members. If consultation was determined by the pharmacist to be necessary, the patient would be required to go to the pharmacy to obtain the medicine.

Mr. Room discussed some possible options the board could consider depending on the full nature of the request. Ms. Shellans indicated that her legal opinion is more limited and that current law only allows for refill prescriptions. Ms. Shellans indicated that expansion to allow for new prescriptions would require a regulatory change.

Ms. Hackworth asked what others services or items are in the room that will house the kiosk and was advised that Walgreens believes the kiosk will be the only item in the room.

Mr. Carter commented that Schedule II controlled substances would be dispensed via the kiosk if allowed by the board.

The kiosk would be filled by only by pharmacists. The prescriptions will be filled at a local Walgreens and delivered to the Kiosk, not filled by a central fill pharmacy.

Mr. Room clarified that under the current regulation, the board lacks the authority to waive the requirement that the kiosk be adjacent to a pharmacy. Further, Mr. Room noted, in that access to a machine not housed in a pharmacy by board staff for investigative purposes could be problematic.

> **Motion: Enforcement Committee:** Deny the request but have the board re-evaluate the regulation and determine if changes are necessary to address emerging technologies.

Committee Member Zee suggested that perhaps Walgreens could work with counsel to develop language that could address the boards concerns as an interim solution to allow for a temporary waiver to be considered at a future committee meeting. Mr. Carter expressed a willingness to work with the board.

Mr. Carter indicated that a few other states allow for the use of a Kiosk as being proposed and offered to survey and provide information to the board.

c. **FOR INFORMATION: Request for a Waiver of Security Prescription Blank Prescribing Requirements for Controlled Substances in a Closed Health Care System**

Attachment 3

Background:

Existing law requires the use of security prescription forms for written prescriptions for controlled substances. Security prescription forms must be printed by state-registered printers and conform to specific requirements to make forgery of these forms difficult. There are few exceptions to the use of these specialized forms when a prescriber writes a prescription.

Schedule III-V drugs may be prescribed orally; only in very limited cases, may Schedule II drugs be orally prescribed.

In 2010, the DEA released Interim Final Rules to permit the e-prescribing of controlled substances, and all e-prescriptions for controlled substances must the DEA's regulatory requirements, including a third-party audit of the computer application certifying that the system meets the requirements of the DEA regulations.

E-prescribing is <u>not</u> faxing (where a prescription is actually written and signed by the prescriber, and a facsimile is transmitted to the pharmacy). Faxing is not allowed for controlled substances, although faxed prescriptions for Schedule III- V prescriptions are sometimes treated as oral prescriptions by pharmacies which if received, must verify the fax with the prescriber's office. (Note, a security prescription form, if faxed, is required to display a "VOID" impression on the faxed document, showing that the fax is not a legitimate written prescription.)

<u>Committee Discussion and Action:</u>

Kaiser Permanente requested an opportunity to address the committee to seek an exemption within Kaiser's closed system of patient care to use plain paper to prescribe controlled substances. The request is provided as **Attachment 3**.

Steve Gray, representing Kaiser Permanente, provided a brief overview of Kaiser Permanente including its closed integrated system. Dr. Gray provided a brief overview of the concerns with their current process and handling of schedule III and IV controlled substance prescriptions. Dr. Gray indicated that the result of their current process is delays in delivering pharmacy services. Instead, Kaiser proposes to print all controlled substances prescriptions for Schedule III and IV drugs on plain white paper, hand this document to the patient, and then have the Kaiser pharmacy access patient electronic records to confirm the controlled drug and quantity are as written on the plain paper "prescription." Dr. Gray indicated that the proposal would reduce drug diversion as well as diversion of security of prescription forms.

Kaiser provided a PowerPoint to discuss the overview of the current system as well as the proposal alternative process. (Copies of the Powerpoint are attached to the committee's meeting minutes.)

Kaiser had previously presented this proposal to the CA Department of Justice, who stated that the proposal appeared to comply with the intent of the law, but this is not an official position of the agency. Dr. Gray also spoke about the security features of the Kaiser system. Dr. Gray indicated that it this system would address the issue of someone calling in a fake oral prescription and well as the diversion of security prescription blanks.

Kaiser was directed by the DOJ to discuss their proposal with the board to ascertain the guidance of the board to determine if the board has concerns with the proposal. This information would then be brought back to the DOJ who establishes the requirement for the security prescription requirement.

Ms. Herold indicated that she firmly believes that the board lacks the authority to act on this provision to grant Kaiser the ability to use non-security forms to prescribed controlled drugs. Ms. Herold indicated that DOJ also lacks the authority to accept this waiver of state law as well. Ms. Herold indicated that she would strongly advise the board to not consider this waiver until the statute is changed.

Dr. Gray advised the committee that the DOJ has indicated that they do not believe that the Health and Safety Code does not prohibit this type of prescribing.

Mr. Room indicated that he would need to discuss this proposal with the DOJ to determine if the law is in fact flexible enough to allow the proposal without a statutory change.

> **Motion:** Move that the board recommend to the DOJ that the board does not have an objection to the plan as set forth by Kaiser for a closed system to use plain paper with the caveat that Kaiser counsel meet with DOJ to discuss the enforcement issues.

Mr. Room has reached out to the Department of Justice, and he has requested that Kaiser provide a legal analysis justifying such an action. A report will be provided to the committee at the next meeting.

d. **FOR INFORMATION:** <u>Board of Pharmacy's Comments on the Drug Enforcement Administration's Proposed Regulations Related to the Disposal of Controlled Substances</u>

Attachment 4

<u>Background:</u>

In 2009, California adopted guidelines for the take back and destruction of unwanted pharmaceuticals from the public so they could be appropriately destroyed and not misused by others or flushed down the drain. However, the guidelines were only guidelines until the DEA promulgated regulations to deal with the collection and destruction of controlled substances.

The DEA developed proposed regulations to deal with the take back and destruction of controlled substances and released them for comment in December 2012, with a final comment date of February 19, 2013. At the February Board Meeting, the board directed that comments be submitted to conform to board policy and California's guidelines in this area.

The board's comments are provided in **Attachment 4**. The general structure and components of the proposed regulations mirror to a high degree California's guidelines.

Committee Discussion and Action:

During the meeting, the committee briefly discussed the board's comments and the proposed regulations. In the coming months, the board may wish to develop provisions to specify how pharmacies and reverse distributors handle unwanted drugs returned for destruction from the public. This is already being requested pursuant to pending legislation in California.

e. **FOR DISCUSSION: Proposal for Statutory Provisions to Prevent a Wholesaler from Purchasing Prescription Medication from a Pharmacy When the Pharmacy Did Not Initially Purchase the Medication from the Wholesaler**

Attachment 5

Background:

California law has provisions to prohibit pharmacies from acting as wholesalers, specifically prohibiting pharmacies from purchasing prescription medication and reselling these medications to other pharmacies or wholesalers, with specific exceptions. These provisions were enacted in 2004 as part of the first e-pedigree law as one method to stop drug diversion, and safeguard the supply chain.

The specific provisions are:

4126.5. Furnishing Dangerous Drugs by Pharmacy
(a) A pharmacy may furnish dangerous drugs only to the following:
    (1) A wholesaler owned or under common control by the wholesaler from whom the dangerous drug was acquired.
    (2) The pharmaceutical manufacturer from whom the dangerous drug was acquired.
    (3) A licensed wholesaler acting as a reverse distributor.
    (4) Another pharmacy or wholesaler to alleviate a temporary shortage of a dangerous drug that could result in the denial of health care. A pharmacy furnishing dangerous drugs pursuant to this paragraph may only furnish a quantity sufficient to alleviate the temporary shortage.
    (5) A patient or to another pharmacy pursuant to a prescription or as otherwise authorized by law.
    (6) A health care provider that is not a pharmacy but that is authorized to purchase dangerous drugs.
    (7) To another pharmacy under common control.
(b) Notwithstanding any other provision of law, a violation of this section may subject the person or persons who committed the violation to a fine not to exceed the

amount specified in Section 125.9 for each occurrence pursuant to a citation issued by the board.

(c) Amounts due from any person under this section on or after January 1, 2005, shall be offset as provided under Section 12419.5 of the Government Code. Amounts received by the board under this section shall be deposited into the Pharmacy Board Contingent Fund.

(d) For purposes of this section, "common control" means the power to direct or cause the direction of the management and policies of another person whether by ownership, by voting rights, by contract, or by other means.

Over the last few years, there has been notice of drug shortages at higher levels than in the past. Desperate providers and patients will pay high prices to obtain the medication they need.   Also over the last few years, the board has identified multiple cases where smaller wholesalers have recruited pharmacies to purchase medication in short supply specifically for the wholesaler. These purchases exceed the allowances authorized in section 4126.5(a)(4) whereby a pharmacy can sell product to alleviate the shortage. By recruiting a number of pharmacies to do such purchasing, the wholesaler can obtain enough volume of a short supply drug to charge very high rates for the medication they are able to obtain. This has occurred in California and it has occurred nationally. **Attachment 5** contains information about the efforts of federal legislators to stop this practice nationally.

Board staff suggest that to prevent California wholesalers from purchasing drugs from pharmacies outside California, that a reciprocal provision be pursued to prevent a California wholesaler from purchasing drugs from a pharmacy if the pharmacy did not initially purchase the drugs form the wholesaler.

Proposed language to do this is provided below.

§ 4126.5. Persons or organizations that pharmacies may furnish with dangerous drugs; violations; offset of amounts due; definitions

(a) A pharmacy may furnish dangerous drugs only to the following, and only the following may receive dangerous drugs furnished by a pharmacy:

(1) A wholesaler owned or under common control by the wholesaler from whom the dangerous drug was acquired.

(2) The pharmaceutical manufacturer from whom the dangerous drug was acquired.

(3) A licensed wholesaler acting as a reverse distributor.

(4) Another pharmacy or wholesaler to alleviate a temporary shortage of a dangerous drug that could result in the denial of health care. A pharmacy furnishing dangerous drugs pursuant to this paragraph may only furnish a quantity sufficient to alleviate the temporary shortage.

(5) A patient or to another pharmacy pursuant to a prescription or as otherwise authorized by law.

(6) A health care provider that is not a pharmacy but that is authorized to purchase dangerous drugs.

(7) To another pharmacy under common control.

(b) Notwithstanding any other provision of law, a violation of this section by either a pharmacy whose primary or sole business is filling prescriptions for patients of long-term care facilities or a person engaged in a prohibited transaction with a pharmacy whose primary or sole business is filling prescriptions for patients of long-term care facilities may subject the person or persons who committed the violation to a fine not to exceed the amount specified in Section 125.9 for each occurrence pursuant to a citation issued by the board.

(c) Amounts due from any person under this section on or after January 1, 2005, shall be offset as provided under Section 12419.5 of the Government Code. Amounts received by the board under this section shall be deposited into the Pharmacy Board Contingent Fund.

(d) For purposes of this section, "common control" means the power to direct or cause the direction of the management and policies of another person whether by ownership, by voting rights, by contract, or by other means.

(e) For purposes of subdivision (b) of this section and subdivision (s) of Section 4301, "long-term care facility" shall have the same meaning given the term in Section 1418 of the Health and Safety Code.

Committee Discussion:

Staff indicated that under investigation is a wholesaler that is purchasing drugs from nonresident pharmacies, drugs that are short supply, and this proposal would prohibit a CA located wholesaler from purchasing drugs from a nonresident pharmacy. In existing law is a prohibition that a CA pharmacy cannot sell drugs to a wholesaler that it did not initially buy the drugs from – with several exception. However the law does not appear to explicitly prohibit such a transaction when the pharmacy involved is not located within CA.

Mr. Room discussed the intent of the legislative proposal and outlined the current law relating to this area. He stated that under current law, a pharmacy is allowed to sell a drug that is currently in stock to a wholesaler to alleviate a shortage. He indicated that three conditions must be met to allow for a sale from a pharmacy to a wholesaler from other than that from which they originally purchased the drugs.

1. The pharmacy already has it in stock

2. The drug for which there is a shortage and

3. A person will be denied health care

Discussion during the meeting was that the committee needs to more fully discuss the topic.

Concern from one attendee was that the legislative proposal would limit the ability for pharmacies and wholesalers to conduct business relationships that ensure patients receive their medications when a shortage occurs. This commenter discussed the type of business he currently operates that allows him to fill a given order for a drug in short supply through a network of wholesalers and to ensure patients receive the medications they need.

Another commenter stated that several pharmacies are confused about what are the preconditions for the limited sales transactions to occur between pharmacies and wholesalers. He recommended that the board should provide clarity on these issues.

No action was taken on this item.

f. **FOR DISCUSSION: <u>Implementation of California's Electronic Pedigree Requirements for Prescription Medication</u>**

This portion of the Enforcement Committee focused on e-pedigree implementation issues. There were no action items from the meeting, but the committee and public had an opportunity to view proposed new regulation language during the meeting on inference, certification (of sales and purchases into the e-pedigree) and inspection (contained in **Attachment 7**). The next committee meeting will provide the public with a chance to provide information specifically on these proposed regulations.

To promote communication, future meetings of the committee will be configured around a large hollow square. Whereas webcasting is a priority, due to staffing changes in the Department of Consumer Affairs, it may be difficult to continue to maintain such broadcasts. Board staff is currently looking at ways to provide these services ourselves.

Below are the general discussions held during this meeting. The meeting minutes provide greater detail, and Powerpoints provided during the meeting are provided at the back of the Enforcement Committee minutes.

1. **Update on the Status of Proposed Regulations to Implement Serialized Numeric Identifiers, Grandfathering and Manufacturer Reporting of How the 50 Percent Threshold of Serialized Products on January 1, 2015 Has been Determined (Proposals to Add Title 16, California Code of Regulations, Sections 1747 and 1747.1)**
   Attachment 6

   The board has compiled the rulemaking file on these regulations, and it is currently undergoing the required review by Administration agencies.

   Copies of the final version of the regulation approved by the board are available in **Attachment 6**.

2. **Presentations and Questions from the Pharmaceutical Supply Chain on Their Readiness to Meet California's Staggered E-Pedigree Implementation Schedule**

   During this part of the meeting, members of the supply chain presented information or discussed issues involving their readiness to implement e-pedigree tracking and tracing. The board encourages such discussion as a way to foster better understanding, to speed and ease implementation, and to identify and resolve issues.

   The committee heard a presentation from Bob Celeste representing GS1. Mr. Celeste provided information the very recently released Implementation Guideline from GS1 to support US pharmaceutical supply chain business practices on pedigree and track and trace. Mr. Celeste indicated that the document is a preliminary document at this point; it is being used by some companies to move forward with pilots, but may change as a result of pilot projects as well as further review of the overall process (this document is provide as an attachment to the Enforcement Committee Minutes).

   Mr. Celeste spoke about the use of the EPCIS standard to comply with the board's law. He indicated that the EPCIS model would appear to be able to comply with the legal requirements for e-pedigree. However, Mr. Celeste indicated that there are some issues surrounding the use of the centralized model, data governance and who will have access to view and see information that still need to be worked out.

   Liz Gallenagh and John Howells representing HDMA provided a presentation focused on the use of drop shipments by members of the supply chain.

During committee discussion, the HDMA representatives stated that members of the supply chain learn in various ways when a product is being drop shipped – there is no one model. The committee also discussed some of the parameters of wholesale brokering and its similarity to drug shipments and how this could compromise the pedigree process. Mr. Room pointed out that the manufacturer designee drop ship model using a third party logistics provider as described would not comply with section 4163.1.

3. **Elements for Possible Regulation Requirements to Permit Inference**

Attachment 7

Mr. Room introduced and described possible regulatory language on inference, certification and expectations on how to access data for purposes of inspections. These regulation proposals are provided in **Attachment 7**.

As explained by Deputy Attorney General Room, California statute requires every trade partner who owns a drug product to be sold in California to verify the product at the unit level. In the absence of action by the board to allow for inference, verification is required at the unit level. The board needs to have data to support what types of inference industry wants.

Since July 2012, the board has three times released written requests seeking specific comments needed to develop possible regulations to authorize inference. The board has received only a few comments in response to these requests for information, and few of the comments received were appropriately responsive to the board's inquiries.

The committee heard various comments on inference. Walgreens spoke in need of inference in their distribution center. When asked what percentage of cases go through their distribution center without being broken down, Walgreens indicated that an unsealed case going through to their pharmacies would be an exception.

Mr. Room again asked for documentation and reemphasized the need for industry members to provide comments in response to board requests for detailed information on inference and drop shipments. This information and detail is necessary to develop appropriate regulation requirements.

Ms. Herold also underscored the need for the board to have comments on the draft language to ensure that the regulation is appropriate, ensures the necessary protections are in place but does not prevent the flow of drugs through the supply chain.

4. **Discussion on the Certification Process to Comply with California's e-Pedigree Law**

At the December 2012 Enforcement Committee Meeting, there were specific questions asked about the certification processes that must be used when certifying sales or purchases of medication to append the e-pedigree.   During the meeting, the committee discussed this subject. Additionally, **Appendix 7** contains draft regulation language on certification and on inspection.

5. **Discussion on the Use of Drop Shipments in the e-Pedigree System**

In March staff released a solicitation request through the board's email notification system that the board was seeking information on drop shipments from members of the supply chain.

In the short time since the release of this request, the board received one comment that was shared with the committee.

g. **FOR INFORMATION: Institute of Medicine Report: Countering the Problem of Falsified an Substandard Drugs**

ATTACHMENT 8

The Institute of Medicine in February released a report on the compromises and problems of US and world drug supplies. This lengthy report describes this problem. It has been added to this agenda only to provide the board and public with knowledge about this problem.

A San Francisco Chronicle article on this report and the problem in general is provided as **Attachment 8.**

h. **FOR INFORMATION: Enforcement Statistics**

ATTACHMENT 9

Attachment 9 will be made available at the board meeting.

e. **FOR INFORMATION: Third Quarterly Report on the Committee's Goals**

ATTACHMENT 10

ENFORCEMENT COMMITTEE MEETING SUMMARY   **ATTACHMENT 11**

A copy of the meeting summary is provided in Attachment 11.

Attachment 1

California State Board of Pharmacy
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STATE AND CONSUMER SERVICES AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
GOVERNOR EDMUND G. BROWN JR.

March 5, 2013

To: Members, Enforcement Committee

Subject: Agenda Item I(a): Request to Store Prescription Records Over Five Years Old Offsite

<u>**Background:**</u>

California has requirements that all pharmacy records be readily retrievable in the licensed premises, and open to inspection by the board. These records are generally required to be retained for at least three years.

California law also permits the offsite storage of records if an offsite waiver has been approved by the board.

<u>**Request:**</u>

Walgreens has requested that because CMS requires storage of records for 10 years, they would like the ability to store records older than five years offsite at a firm that specializes in records storage. The specific request follows this page.

A representative of Walgreens will attend this meeting to provide information about the request.

January 14, 2013

Ms. Virginia Herold
Executive Officer
California State Board of Pharmacy
1625 N. Market Blvd., N219
Sacramento, CA 95834

Dear Ms. Herold,

Walgreens requests to be placed on the next Enforcement Committee on March 21, 2013. We are seeking a waiver for off-site retention of prescription records as stated in Section 1707 of Article 2 of Division 17 of Title 16 of the California Code or Regulations.

In order to comply with CMS recordkeeping requirements, Walgreens is looking to retain off-site in conjunction with Iron Mountain all prescription hard copy records that are older than 5 years. Iron Mountain is an information management company that manages assets, electronic records, document imaging, business records and secure shredding for organizations worldwide. Iron Mountain's facilities meet the requirements of National Archives of Records Administration (NARA) 36 Code of Federal Regulations Part 1234 as well as Federal Emergency Management Agency (FEMA) Continuity of Operations Plan (COOP) requirements.

These records will be retained for an additional 5 years to be in compliance with the CMS Medicare Prescription Drug Improvement and Modernization Act requirements to keep records for 10 years. Due to these special circumstances, we would like to appear before the Board to present this request.

Thank you for considering this waiver, and I look forward to meeting with the Board at the next meeting.

Please call me if you have any questions.

Sincerely,

Al Carter, Pharm.D.
Director, Professional Affairs
Walgreen Co.
200 Wilmot Rd., MS #2161
Deerfield, IL 60015
Phone 847-315-3940
Fax 847-315-3109
Al.Carter@Walgreens.com

Attachment 2a

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STATE AND CONSUMER SERVICES AGENCY
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March 5, 2013

To: Members, Enforcement Committee

Subject: Agenda Item I (b): Request to Install an Automated Drug Delivery Device (or Kiosk) in Workplace Centers

Background:

Several years ago, the board promulgated regulations (16 California Code of Regulation section 1713) to allow for the use of automated delivery devices, which are markedly like vending machines, to permit the furnishing of refill medication in specified circumstances. These circumstances include, that the patient must opt in to use the machine, the medication to be refilled through the machine is appropriate. The conditions are listed below in the highlighted segment of section 1713.

1713. Receipt and Delivery of Prescriptions and Prescription Medications Must be To or From Licensed Pharmacy

(a) Except as otherwise provided in this Division, no licensee shall participate in any arrangement or agreement, whereby prescriptions, or prescription medications, may be left at, picked up from, accepted by, or delivered to any place not licensed as a retail pharmacy.

(b) A licensee may pick up prescriptions at the office or home of the prescriber or pick up or deliver prescriptions or prescription medications at the office of or a residence designated by the patient or at the hospital, institution, medical office or clinic at which the patient receives health care services. In addition, the Board may, in its sole discretion, waive application of subdivision (a) for good cause shown.

(c) A patient or the patient's agent may deposit a prescription in a secure container that is at the same address as the licensed pharmacy premises. The pharmacy shall be responsible for the security and confidentiality of the prescriptions deposited in the container.

(d) A pharmacy may use an automated delivery device to deliver previously dispensed prescription medications provided:

(1) Each patient using the device has chosen to use the device and signed a written consent form demonstrating his or her informed consent to do so.

(2) A pharmacist has determined that each patient using the device meets inclusion criteria for use of the device established by the pharmacy prior to delivery of prescription medication to that patient.

(3) The device has a means to identify each patient and only release that patient's prescription medications.

(4) The pharmacy does not use the device to deliver previously dispensed prescription medications to any patient if a pharmacist determines that such patient requires counseling as set forth in section 1707.2(a)(2).

(5) The pharmacy provides an immediate consultation with a pharmacist, either in-person or via telephone, upon the request of a patient.

(6) The device is located adjacent to the secure pharmacy area.

(7) The device is secure from access and removal by unauthorized individuals.

(8) The pharmacy is responsible for the prescription medications stored in the device.

(9)   Any incident involving the device where a complaint, delivery error, or omission has occurred shall be reviewed as part of the pharmacy's quality assurance program mandated by Business and Professions Code section 4125.

(10)   The pharmacy maintains written policies and procedures pertaining to the device as described in subdivision (e).

(e)   Any pharmacy making use of an automated delivery device as permitted by subdivision (d) shall maintain, and on an annual basis review, written policies and procedures providing for:

(1)   Maintaining the security of the automated delivery device and the dangerous drugs within the device.

(2)   Determining and applying inclusion criteria regarding which medications are appropriate for placement in the device and for which patients, including when consultation is needed.

(3)   Ensuring that patients are aware that consultation with a pharmacist is available for any prescription medication, including for those delivered via the automated delivery device.

(4)   Describing the assignment of responsibilities to, and training of, pharmacy personnel regarding the maintenance and filing procedures for the automated delivery device.

(5)   Orienting participating patients on use of the automated delivery device, notifying patients when expected prescription medications are not available in the device, and ensuring that patient use of the device does not interfere with delivery of prescription medications.

(6)   Ensuring the delivery of medications to patients in the event the device is disabled or malfunctions.

(f)   Written policies and procedures shall be maintained at least three years beyond the last use of an automated delivery device.

(g)   For the purposes of this section only, "previously-dispensed prescription medications" are those prescription medications that do not trigger a non-discretionary duty to consult under section 1707.2(b)(1), because they have been previously dispensed to the patient by the pharmacy in the same dosage form, strength, and with the same written directions.

In 2009-10, Pharmacist Consultant Philip Burgess, on behalf of a manufacturer of one of these machines (Asteres), sought an exemption to permit the use of these machines in areas away from adjacent to the licensed pharmacy premises. The board did not approve the request, and requested more information about how and where the kiosks would be used. One concern was that the board considered that it lacked the ability to provide the exemption sought (which would have required a regulation change). There was no further interest pursued by Asteres after the January 2010 meeting. Materials covering some of these discussions are provided in Attachment Agenda Ib.

At this meeting:

Walgreens has requested an opportunity to address the board to seek a waiver of 1713 to permit the use of an automated delivery device in a workplace setting, away from a pharmacy. A copy of this request follows this page.

Representatives of Walgreens will attend the meeting and provide the presentation.

January 18, 2011

Ms. Virginia Herold
Executive Officer
California State Board of Pharmacy
1625 N. Market Blvd., N219
Sacramento, CA 95834

Dear Ms. Herold,

Walgreens requests to be placed on the next Enforcement Committee on March 21, 2013. We are seeking a waiver to allow for the placement of an automated drug delivery device (kiosk) at a company worksite of which an inpatient clinic is located without an outpatient pharmacy. As stated in Section 1713 of Article 2 of Division 17 of Title 16 of the California Code or Regulations, a licensee may pick up prescriptions at the office or home of the prescriber or pick up or deliver prescriptions or prescription medications at the office of or a residence designated by the patient or at the hospital, institution, medical office or clinic at which the patient receives health care services.

Walgreens would like to request the capability to place this automated delivery device on the campus of a worksite inpatient clinic to provide pharmacy services to these employees.

Thank you for considering this waiver, and I look forward to meeting with the Board at the next meeting.

Please call me if you have any questions.

Sincerely,

Al Carter, Pharm.D.
Director, Professional Affairs
Walgreen Co.
200 Wilmot Rd., MS #2161
Deerfield, IL 60015
Phone 847-315-3940
Fax 847-315-3109
Al.Carter@Walgreens.com

Attachment 2b

Ms. Herold:

On behalf of Asteres, we hereby request an appearance before the
California Board of Pharmacy at the January 20/21 meeting in
Sacramento.

The purpose of our appearance will be to seek approval for the
installation of an automated prescription "pick up" system in a
hospital environment whereby the unit is not directly attached to the
pharmacy.

Upon review of Section 1713, we feel that the Board has regulatory
authority to grant this request based upon Paragraph 1713 (b) which
states in part:

"In addition, the Board may, in its sole discretion, waive application
of subdivision (a) for good cause. Subdivision (a) contains the
language prohibiting the picking up of prescriptions from "any place
not licensed as a retail pharmacy". We will be prepared to justify this
action by the Board demonstrating how that the unit will be in a high-
traffic, secure area on the hospital campus and that a telephone
installation immediately adjacent to the unit will allow readily
available access by the patient to a pharmacist for counseling.

Failing this argument, then we would request a specific waiver from
Section 1713 (d) (6) requiring that "the device is located adjacent to
the secure pharmacy area". We are prepared to have representatives
appear from California hospitals to represent to the Board that by
allowing flexibility in the placement of these "pick-up" devices on
their campuses, that the net result will be to improve patient
compliance and thereby improve patient care. Asteres will present past
history to show to the Board that these devices can be installed in an
area not adjacent to the pharmacy, yet in a secure manner..as well as
in a manner where counseling by a pharmacist to the patient will be
equally if not more readily available than in a standard retail
environment..

Thank you for your consideration.

Phil

Philip P. Burgess, RPh, MBA
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www.philburgessconsulting.com

Title 16, California Code of Regulations

1713. Receipt and Delivery of Prescriptions and Prescription Medications Must be to or from Licensed Pharmacy

(a) Except as otherwise provided in this Division, no licensee shall participate in any arrangement or agreement, whereby prescriptions, or prescription medications, may be left at, picked up from, accepted by, or delivered to any place not licensed as a retail pharmacy.

(b) A licensee may pick up prescriptions at the office or home of the prescriber or pick up or deliver prescriptions or prescription medications at the office of or a residence designated by the patient or at the hospital, institution, medical office or clinic at which the patient receives health care services. In addition, the Board may, in its sole discretion, waive application of subdivision

(a) for good cause shown.

(c) A patient or the patient's agent may deposit a prescription in a secure container that is at the same address as the licensed pharmacy premises. The pharmacy shall be responsible for the security and confidentiality of the prescriptions deposited in the container.

(d) A pharmacy may use an automated delivery device to deliver previously dispensed prescription medications provided:

(1) Each patient using the device has chosen to use the device and signed a written consent form demonstrating his or her informed consent to do so.

(2) A pharmacist has determined that each patient using the device meets inclusion criteria for use of the device established by the pharmacy prior to delivery of prescription medication to that patient.

(3) The device has a means to identify each patient and only release that patient's prescription medications.

(4) The pharmacy does not use the device to deliver previously dispensed prescription medications to any patient if a pharmacist determines that such patient requires counseling as set forth in section 1707.2(a)(2).

(5) The pharmacy provides an immediate consultation with a pharmacist, either in-person or via telephone, upon the request of a patient.

(6) The device is located adjacent to the secure pharmacy area.

(7) The device is secure from access and removal by unauthorized individuals.

(8) The pharmacy is responsible for the prescription medications stored in the device.

(9) Any incident involving the device where a complaint, delivery error, or omission has occurred shall be reviewed as part of the pharmacy's quality assurance program mandated by Business and Professions Code section 4125.

(10) The pharmacy maintains written policies and procedures pertaining to the device as described in subdivision (e).

(e) Any pharmacy making use of an automated delivery device as permitted by subdivision (d) shall maintain, and on an annual basis review, written policies and procedures providing for:

(1) Maintaining the security of the automated delivery device and the dangerous drugs within the device.

(2) Determining and applying inclusion criteria regarding which medications are appropriate for placement in the device and for which patients, including when consultation is needed.

(3) Ensuring that patients are aware that consultation with a pharmacist is available for any prescription medication, including for those delivered via the automated delivery device.

(4) Describing the assignment of responsibilities to, and training of, pharmacy personnel regarding the maintenance and filing procedures for the automated delivery device.

(5) Orienting participating patients on use of the automated delivery device, notifying patients when expected prescription medications are not available in the device, and ensuring that patient use of the device does not interfere with delivery of prescription medications.

(6) Ensuring the delivery of medications to patients in the event the device is disabled or malfunctions.

(f) Written policies and procedures shall be maintained at least three years beyond the last use of an automated delivery device.

(g) For the purposes of this section only, "previously-dispensed prescription medications" are those prescription medications that do not trigger a non-discretionary duty to consult under section 1707.2(b)(1), because they have been previously dispensed to the patient by the pharmacy in the same dosage form, strength, and with the same written directions.

Authority cited: Sections 4005, 4075, and 4114 Business and Professions Code. Reference: Sections 4005, 4052, 4116 and 4117 Business and Professions Code.

IX. Licensing Committee Report

a.   Report of the Committee Meeting Held December 3, 2009

    1.   Request to Modify Title 16 California Code of Regulations Section 1713(d) Regarding the Requirement that Automated Dispensing Machines Be Adjacent to the Secure Pharmacy Area

Mr. Weisser provided that in 2005 and 2006, the board discussed and eventually promulgated a regulation to allow automated dispensing machines in pharmacies to dispense refill medications -- if requested by the patient and approved by the pharmacist. He stated that this was a use of emerging technology and several pharmacies had sought the board's authority to install such machines in their pharmacies to provide patients with afterhours access (as well as access during times when the pharmacy was open) to refills. Mr. Weisser explained that a patient could pick up refill medication, if approved by the pharmacy, from a vending-like machine using a credit card for payment and not specifically deal with the pharmacy staff. He advised that the machine was to be located near – specifically adjacent -- to the physical area of the pharmacy.

Mr. Weisser provided that a number of conditions were built into the regulations to provide for assurance patients would not be required to use these machines for refills if they were not supportive.

Mr. Weisser advised that this regulation was promulgated cautiously. He stated that throughout 2006, the board modified and adopted the regulation now in effect as section 1713. Mr. Weisser provided that in January 2007, the regulation actually took effect.

Mr. Weisser provided that during the meeting, the committee heard a presentation from Phil Burgess, representing Asteres, one vendor of these automated delivery devices. He stated that Mr. Burgess is seeking a waiver to the requirements in 1713 (d)(6) which requires that the delivery device be located adjacent to the secure pharmacy area. Mr. Weisser explained that in making the request, Mr. Burgess stated that they would like to place the device in a secure area that is readily accessible to the patient and that a telephone would be placed adjacent to the device for patients that wished to speak with a pharmacist.

Presentation - Phil Burgess and Mike de Bruin, Asteres

Phil Burgess, representing Asteres, provided an overview of ScriptCenter, a 24/7 automated pharmacy prescription pick-up machine including the registration and authorization process. He reviewed patient safety and security benefits and

added that ScriptCenter has successfully delivered over 450,000 prescriptions without one delivery error.

Mr. Burgess requested that the board waive regulation Section 1713(d)(6) regarding the placement of automated medication dispensing machines in hospitals.

Board Discussion

Mr. Brooks sought clarification regarding how a pharmacy obtains a ScriptCenter machine.

Mike de Bruin provided that there are multiple methods of acquisition strategies.

Burgess provided that each machine will have a phone located adjacent to the machine to allow the patient to immediately contact the pharmacist.

Mr. Lippe asked if the patient will be charged a transaction fee.

Mr. Burgess provided that no transaction fee is charged.

Mr. de Bruin provided that the machine will collect the patient's insurance co-pay.

Ms. Herold sought clarification regarding if it is intended for the machine to be made available to both hospital staff and patients.

Mr. Burgess indicated that Asteres would like the machine to be available to both hospital staff and patients. He provided that only refill prescriptions would be filled and the machine would only be located on the hospital campus in a secure environment, not necessarily in a hospital.

Mr. Room asked if any machines have been installed outside of a hospital campus.

Mr. de Bruin provided that machines have been installed in other areas in other states.

Mr. Room provided that this request may not be granted under a Section 1713 waiver.

Discussion continued regarding the ScriptCenter system and its applicability to pharmacy law and Section 1713. Advantages and disadvantages of the system were evaluated. Concern was expressed that this process may depersonalize the pharmacist and prescription service. It was clarified that in the event a waiver is granted, the waiver would be granted to the licensed facility and not to Asteres.

Public Comment

Dr. Allan Schaggs, representing Catholic Healthcare West (CHW), provided that CHW would like to provide ScriptCenter as a service to their employees.

Dr. Castellblanch sought clarification regarding why the waiver is also being requested for patients.

Mr. Burgess provided that the machine can benefit the spouses of employees and children of employees.

Discussion continued regarding the request and the placement of the machine in a secure area on the hospital campus. Concern was expressed that the request does not specify placement of the machine.

Dr. Steve Gray, representing Kaiser Permanente, offered support for the ScriptsCenter concept. He encouraged the board to grant a waiver under Section 1713 (b) for employees and to consider further discussion of a waiver for other patients.

Mr. Weisser sought clarification regarding mail order prescriptions and patient requests for phone consultations with a pharmacist.

Dr. Gray provided that in the rare event that a patient does have a question, they can often get their questioned answered faster by calling a pharmacist than if they were to wait in line at a pharmacy.

Mr. Burgess provided that the ScriptsCenter machine allows for a pharmacist to be available to the patient when the adjacent pharmacy is closed during off hours.

Ms. Herold provided that pharmacies using such a device are required to provide immediate access to a telephone for patients to contact a 24-hour pharmacy in the event their pharmacy is closed.

Ms. Herold indicated that board staff will provide some guidelines to assist Asteres with providing the required clarification regarding their request.

There was no additional board discussion or public comment.

2. Final Review on Parameters for Recalls in Hospitals

Mr. Weisser provided that during the spring of 2008, the board identified 94 hospital pharmacies with recalled heparin still within the facilities, two to three months following the last recall.

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STATE AND CONSUMERS SERVICES AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
ARNOLD SCHWARZENEGGER, GOVERNOR

Licensing Committee Report

Members:
Stan Weisser, RPh, Chairperson
Randy Kajioka, PharmD
Ramón Castellblanch, Public Member

IX. LICENSING COMMITTEE REPORT AND ACTION

a. Report of the Committee Meeting Held December 3, 2009

1. **FOR DISCUSSION:** <u>Request to Modify Title 16 California Code of Regulations Section 1713(d) Regarding Requirement that Automated Dispensing Machines Be Adjacent to the Secure Pharmacy Area</u>

Attachment 1

Background

In 2005 and 2006, the board discussed and eventually promulgated a regulation to allow automated dispensing machines in pharmacies to dispense refill medications -- if requested by the patient and approved by the pharmacist. This was a use of emerging technology and several pharmacies had sought the board's authority to install such machines in their pharmacies to provide patients with afterhours access (as well as access during times when the pharmacy was open) to refills. Basically, a patient could pick up refill medication, if approved by the pharmacy, from a vending-like machine using a credit card for payment and not specifically deal with the pharmacy staff. The machine was to be located near – specifically adjacent -- to the physical area of the pharmacy.

A number of conditions were built into the regulations to provide for assurance patients would not be required to use these machines for refills if they were not supportive. A copy of the final regulation is provided below.

This regulation was promulgated cautiously. Throughout 2006, the board modified and adopted the regulation now in effect as section 1713. In January 2007, the regulation actually took effect.

During the meeting, the committee heard a presentation from Phil Burgess, representing Asteris, one vendor of these automated delivery devices. Mr. Burgess is seeking a waiver to the requirements in 1713 (d)(6) which requires that the delivery device be located adjacent to the secure pharmacy area. In making the request, Mr. Burgess stated that they would like to place the device in a secure area that is readily accessible to the patient and that a telephone would be placed adjacent to the device for patients that wished to speak with a pharmacist.

Mr. Burgess will provide a presentation to the board during the meeting.

A written copy of the waiver request as well as a copy of CCR 1713 is provided in **Attachment 1**. At the request of the committee, staff will be prepared to discuss various options for the board to consider.

2. FOR ACTION: <u>Final Review of Parameters for Recalls in Hospitals</u>

During the spring of 2008, the board identified 94 hospital pharmacies with recalled heparin still within the facilities, two to three months following the last recall. The board cited and fined the hospital pharmacies and pharmacists-in-charge of these pharmacies. However, because many of these hospitals and PICs have appealed the citations and fines, board members cannot discuss the specific parameters of any of these cases without recusing themselves from voting on the specific case in the future should they be appealed to the Office of Administrative Hearings.

Over the last year, the board convened a two-board member task force to work with relevant associations, regulators, hospitals, wholesalers and patient advocates on ways to improve recalls, and other changes needed to provide for improved drug distribution and control within a hospital. Three meetings were held, and at the last meeting in September, a draft Best Practices document was refined. A draft document establishing the parameters for recalls in hospitals was one major outcome of these meetings.

The revised document will be provided during the board meeting. The last step will be a presentation to the board for ratification and future publication in the board's newsletter.

3. FOR INFORMATION: <u>Emergency and Disaster Response Planning: Update on the H1N1 Emergency Response Activities in California</u>

For more than one year, health care providers, policy makers and governments worldwide have been dealing with the H1N1 flu worldwide pandemic.

In California, the board has provided assistance. This has included:
* Sharing our subscriber alert system to advise licensees of directives from the California Department of Public Health
* Ensuring the expedited licensing of storage locations for the H1N1 vaccines
* Establishing a specialized list of compounding pharmacies that the Department of Public Health can access if special, compounded formulations of medications are needed
* Transferring messages from board licensees that need a response or intervention from the Department of Public Health's Emergency Planning and Response Branch, Emergency Preparedness Office

Board staff continues to work closely with the Department of Public Health to assist in ways that will benefit the public.

In order to ensure that the board can act quickly to activate the board's emergency response policy in response to a sudden declared crisis, at the October Board Meeting, the board voted that:

Attachment 3

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STATE AND CONSUMER SERVICES AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
GOVERNOR EDMUND G. BROWN JR.

March 5, 2013

To: Members, Enforcement Committee

Subject: Agenda Item I (c): Request for a Waiver of Security Prescription Blank Prescribing Requirements for Controlled Substances in a Closed Health Care System

Background:

Existing law requires the use of security prescription forms for written prescriptions for controlled substances. Security prescription forms must be printed by state-registered printers and conform to specific requirements to make forgery of these forms difficult. There are few exceptions to the use of these specialized forms when a prescriber <u>writes</u> a prescription.

Schedule III-V drugs may be prescribed orally; only in very limited cases, may Schedule II drugs may be orally prescribed.

In 2010, the DEA released Interim Final Rules to permit the e-prescribing of controlled substances, and all e-prescriptions for controlled substances must the DEA's regulatory requirements, including a third-party audit of the computer application certifying that I meets the requirements of the DEA regulations.

E-prescribing is <u>not</u> faxing (where a prescription is actually written and signed by the prescriber, and a facsimile is transmitted to the pharmacy). Faxing is not allowed for controlled substances, although faxed prescriptions for Schedule III- V prescriptions are sometimes treated as oral prescriptions by pharmacies which if received, must verify the fax with the prescriber's office. (Note, a security prescription form, if faxed, is required to display a "VOID" impression on the faxed document, showing that the fax is not a legitimate written prescription.)

Request:

Kaiser Permanente has requested an opportunity to address the committee to seek an exemption within Kaiser's closed system of patient care to use plain paper to prescribe controlled substances. Their request is attached on the next page.

Representatives of Kaiser Permanente will appear at this meeting to provide the presentation.

Temporary Alternative Manual Process for Schedule III-V Prescriptions

Requested Kaiser Permanente Agenda Item
Board of Pharmacy Enforcement Committee March 14, 2013

Executive Summary. Kaiser Permanente (KP) has been reviewing our current manual system to process Schedule III-V controlled substance prescriptions. This review is in response to pharmacy, medical staff and member concerns about the impact of the current process on the quality of care and service we deliver in our pharmacies. In addition, there are concerns regarding the negative impact of the current manual process on the productivity of pharmacy, nursing and medical staff members, and thereby the cost to our patients, payors and the public. KP proposes to adopt a more secure method of processing Schedule III-V controlled substance prescriptions that takes advantage of its *Closed System of Prescribers and Proprietary Pharmacies* that share access to one electronic medical record (EMR) system in order to address these and other concerns.

Problem: The current manual process produces a Schedule III-V controlled substance prescription printed on plain paper printed from the KP EMR system. These prescriptions are subsequently hand signed and dated by the provider and faxed to a KP pharmacy. Though fully meeting DEA and California DOJ and BOP requirements, this method does cause delays in processing these prescriptions which negatively impacts the quality of care and service for our patients and ultimately generates unnecessary expense to our members and payors due to productivity issues. To address these issues long term, KP is pursuing an e-prescribing process for all prescriptions within our EMR and pharmacy systems. However, the current projected timeframe for vendor certification, pilot and program-wide implementation within California is likely at least 18 months away.

Proposed *Temporary* Alternative Manual Process: KP proposes a temporary alternative manual process, that is fully compliant with current DEA requirements. We would continue to print these prescriptions on plain paper from the KP EMR system and require the provider's original ink signature and date. However, instead of faxing these prescriptions to the KP pharmacy, we would instead provide the patient the original printed, signed and dated prescription for filling at a KP pharmacy. The KP pharmacy would then match this original prescription with the EMR order transmitted to the pharmacy system in order to be a valid prescription for filling and dispensing.

This proposed and more secure method will meet the objectives of the Secure Prescription Blank program, administered by the DOJ and described in Health and Safety Code Sections 11161.5 and 11162.1. In addition, it will also help to meet the objectives of H&S Code section 11164(b)(1) for ensuring the security, integrity, authority, and confidentiality of the prescription. Most importantly, it will help to address the quality of care, service, productivity, cost and other concerns with the current manual process. Representatives of the DOJ and others have expressed support with a recommendation to present this compliant temporary alternative process to the Board of Pharmacy for information.

Patients receiving a Schedule III-V prescription from a KP provider will still be able to fill the prescription at a non-KP pharmacy if they desire through the issuance of a secured personalized prescription or a verbal order to the non-KP pharmacy. Finally, upon the implementation of a certified e-prescribing system within KP, this temporary alternative manual process would be discontinued.

Attachment 4

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STATE AND CONSUMER SERVICES AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
GOVERNOR EDMUND G. BROWN JR.

February 19, 2013

Drug Enforcement Administration

Docket No. DEA-316

Submitted electronically to http:www.regulations.gov

Dear Drug Enforcement Administration:

The California State Board State Board of Pharmacy is grateful for this opportunity to provide comments to the Drug Enforcement Administration on its proposal to establish parameters for the take back and destruction of unwanted controlled substances that have been dispensed to patients. We recognize the complexity of the task before the DEA in developing these regulations and we look forward to the enactment of the proposals, we hope with the several modifications we suggest below.

The California State Board of Pharmacy regulates nearly 140,000 licensees who dispense, store and ship prescription drugs and devices throughout, from and into California. This includes both individuals and firms including pharmacies, clinics, wholesalers, pharmacists and the designated representatives who are the licensed staff who work in wholesaler facilities.   Under the general category of wholesaler, the board specifically licenses reverse distributors and brokers (who do not take possession but arrange for the sale of prescription medication).

California is the largest board of pharmacy in the US, and we work feverishly to secure our statutory mandate of consumer protection. In pursuit of this mandate, the board regulates the quality of the pharmaceutical products dispensed as well as the pharmacy services provided to patients. For a number of years, the appropriate disposal of prescription medication, coupled with escalating drug diversion and the growing prescription drug abuse problems have commanded the board's enforcement and educational efforts.

California is also at the forefront of issues surrounding the health of patients and possible jeopardy posed by unscrupulous "entrepreneurs," who buy and sell prescription drugs illegally and damage the state's (and nation's) drug supply. Patients and practitioners are ignorant of the potential for and presence of counterfeit or adulterated medication in the US pharmaceutical supply chain, and simply change therapy when a prescribed drug regimen no longer works.

Over the last decade, the board has aggressively undertaken innovative approaches to secure the quality of pharmaceuticals that are dispensed to patients in California. This includes:
- E-pedigree requirements to establish a comprehensive tracking system for the sale of each container of prescription medication dispensed to California patients, tracking and certifying ownership from the manufacturer, to the wholesaler, to the pharmacy or practitioner. Beginning in 2015 when the requirements become effective over a 2.5 year basis, e-pedigree requirements will permit the identification (and thus enable better investigation and prosecution) of suspect medication at the point it enters the pharmaceutical supply chain.

- Aggressive enforcement of financial sanctions for entities purchasing prescription medication from unlicensed sources ($5,000 per invoice, resulting in fines of hundreds of thousands of dollars).
- Issuance of fines to pharmacies filling internet prescriptions illegally where there is no legitimate prescription for the transaction ($25,000 per "prescription" dispensed, resulting of fines up to $100 million).
- Identification and discipline of pharmacies purchasing drugs not for dispensing to patients but exclusively for resale to wholesalers. Despite a specific prohibition in California enacted in 2004 to prevent a pharmacy from reselling medication to any wholesaler except for returns to the wholesaler that sold the pharmacy the medication initially, the board continues to identify new pharmacy practices involving such sales. Often these sales transactions involve medication in short supply, for which desperate providers and patients will pay high amounts. Such manipulation by pharmacies and wholesalers documented by the board has resulted in price increases to patients exceeding 6,000 percent.
- Hosting educational forums, jointly with the Drug Enforcement Administration, to educate pharmacists about the dangers of prescription drug abuse, drug diversion issues, corresponding responsibility and pharmacy robberies.
- Cooperative joint investigations of board licensees with the Drug Enforcement Administration and other law enforcement agencies to identify and prosecute criminal drug diversion, particularly involving controlled substances.

California has a considerable stake in addressing the disposal of prescription medication. With over 12 percent of the nation's population, 650 million prescriptions were dispensed to patients in California in 2011 out of the total of 4 billion prescriptions dispensed nationally that year. Not all of these medications would have been consumed -- leaving California with likely the largest unwanted drug disposal problems and issues in the country.

Today, there is a considerable illegal movement of prescription medication, including controlled substances, that has been dispensed to patients but ends up being returned/resold to pharmacies and wholesalers. These entities refill manufacturers' containers, and then resell these drugs into the drug supply where they are re-dispensed to unknowing patients. In recent years, the board has encountered multiple cases of this "recycling" in multiple California pharmacies. Often these drugs are obtained from skilled nursing facilities, where the facility and patients no longer have use for them, and destruction would cost the facility money. Instead pharmacies take these drugs back, remove them from blister packs and redispense or resell them.

We have disciplined multiple pharmacies for doing this, but are certain we have not discovered all pharmacies performing such activities. Obtaining drugs from such sources is considerably cheaper than purchasing drugs from legitimate sources. However, identifying such practices is quite difficult for a regulator. In the last two years, the FDA and other law enforcement agencies have identified at least three large scale "recycling" operations, where patients and others have resold dispensed medication back to brokers who repackage into manufacturers' containers and resell the products to wholesalers and pharmacies. We know that two of these three cases involve prescription drugs in California. Specifically:
- $250m worth of HIV medications in New York, some of which were likely shipped to and dispensed in California by a pharmacy linked in ownership with the New York pharmacies indicted

- $500m worth of HIV medications also in New York discovered by the NY AG's Office
- $498m worth of prescription drugs collected from California patients in a federal indictment filed in late 2012.

In 2008, pursuant to legislation enacted in California, guidelines for drug take back programs were developed by several state agencies, including this board. These policies could not be mandated until the Drug Enforcement Administration completed its work on the take back and destruction of controlled substances. In many ways, the Drug Enforcement Administration's proposed federal regulations for destruction of previously dispensed controlled substances support these California guidelines for drug take back programs, which encourage voluntary ongoing collection programs, special event collection, and mail back programs.

Our recommendations are in the form of general comments:

1. **We generally support the framework for the return and destruction of controlled substances as provided for in these proposed regulations. The growing prescription drug abuse and diversion issues in the US require action and such a regulatory framework.**
2. **We find no reference to brokering within the proposed regulations and believe that the proposed regulations do not permit brokering of previously dispensed controlled substances. However, we respectfully request that the DEA prohibit this activity specifically in these regulations. We believe that if left unchecked, the activities of brokers will complicate attempts to document and identify the activities of those entities handle the destruction of unwanted medication.**
3. **The board strongly supports the "commingling, do not sort" provisions of the proposed regulations. The sorting of pharmaceuticals collected in a drug take back program, when done by a pharmacy, reverse distributor or any entity poses a huge opportunity for diversion. In fact, we cannot envision another reason for sorting drugs except to secure a cache of specific drugs.**
4. **Regarding the non-retrievable method of destruction described in the general comments of the regulation package: we fully support commingling of prescription drugs with controlled drugs and even over the counter drugs at collection sites. We strongly support the prohibition against opening the collection devices and container linings, or sorting of collected pharmaceuticals.**

   However, the board now believes that the safest and surest way to ensure previously dispensed medication does not reenter the supply chain as a commercial product is to render the returned medication unusable: specifically to grind it up at the collection bin so that returned pharmaceuticals are nonsalable. As long as the medication can be differentiated as individual pills, it poses potential for being sorted and reintroduced into the supply chain. Grinders (like a coffee grinder or garbage disposal) could readily be added to collection bins at minimal expense to ensure no subsequent "recycling" occurs of the donation -- and in a manner that does not permit fingers to enter the grinding device.

   With implementation of such grinders, regulators can be less concerned that the collected drugs will again become part of the nation's drug supply, permitting redirection of limited enforcement staff to other diversion activities.

5. **We strongly urge that any pharmacy that agrees to accept drugs from nursing homes be required to similarly destroy and grind the medication at the time it is identified by the facility**
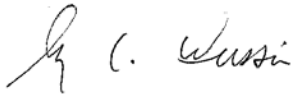
as unwanted waste. The attached photos taken during board investigations document issues we have discovered with drugs being returned to pharmacies where they are recycled to unknowing nursing home patients and other patients, principally from the large volume of medication targeted for destruction in these facilities.

Once a secure disposal system is developed, it could be made available to residential assisted living homes, where there is often no medical staff onsite, but drug disposal problems also exist.

Prescription drug abuse is a serious and growing problem in the US. We share the Drug Enforcement Administration's proposed requirements that reverse distributors, mail back programs, and collection programs offer the public options to dispose of unwanted pharmaceuticals, specifically the unique challenges of controlled substances. Yet from years of experience regulating pharmacies, wholesalers and reverse distributors, we do not want to see additional compromise in the quality of the state's and US pharmaceutical supply caused by opportunists who may pose as pharmacists, pharmacies, reverse distributors or others.   The regulations proposed by the Drug Enforcement Administration are a good start. However, we respectfully assert that all drug take back programs involving previously dispensed medication should ensure the pulverization of medication returned so the remnants are worthless.

Thank you for this opportunity to comments on these important requirements. Please do not hesitate to contact the executive officer with questions.

Sincerely,

STAN WEISSER
President

Sincerely,

VIRGINIA HEROLD
Executive Officer

cc: Photos

Attachment 5

August 28, 2012

Senate Commerce Committee Report on Drug Shortages and the Gray Market "Where Have They All Gone"

Drug shortages continue to make the headlines in both mainstream media and on Capitol Hill. According to drug shortage tracking conducted by the Food and Drug Administration's (FDA) Center for Drug Evaluation and Research (CDER) and the American Society of Health-System Pharmacists (ASHP), drug shortages more than quadrupled between 2005 and 2011. For example, CDER reported that drug shortages increased from 61 in 2005 to 251 in 2011.

FDA defines a drug shortage as "a situation in which the total supply of all clinically interchangeable versions of an FDA-regulated drug is inadequate to meet the current or projected demand at the patient level."

To address this issue, Congress passed in July the Food and Drug Administration Safety and Innovation Act (FDASIA), which gives FDA significant new authorities to combat drug shortages, as we previously reported. While numerous causes for drug shortages have been identified, one serious problem remains: the "gray market." Consequently, the U.S. Senate Commerce, Science and Transportation Committee recently held a hearing and published a report addressing the gray market.

Background on Congressional Investigation

The rising number of drug shortages has been concentrated primarily in the area of generic sterile injectable drugs, liquids packaged in sterile glass vials that are

"parenterally" administered to the body through syringes or an intravenous (i.v.) administration set. Drugs administered in this manner reach their target treatment area more quickly than oral drugs, but also carry greater risks of infection and complications caused by incorrect dosages. Administering a drug intravenously usually requires a trained health care professional who can carefully monitor the dosage and the patient's reaction to the drug. As a result,

drug shortages are affecting mostly acute care patients being treated by providers in hospitals and out-patient facilities.

Of the 251 drug shortages the CDER reported in 2011, 182 of the shortages (73%) involved sterile injectables.   An October 2011 analysis of short-supply drugs conducted by the IMS Institute for Healthcare Informatics also found that most of the reported shortages involved generic sterile injectable drugs. The largest numbers of drugs in this group (20) were sterile injectables used in chemotherapy treatment for cancer patients. The sterile injectables in shortage have also included frequently-used items such as anesthetics for surgery, "crash cart" drugs used in emergency rooms, and electrolytes for intravenous feeding.

In October 2011, House Committee on Oversight and Government Reform Ranking Member Elijah Cummings opened this investigation by sending information request letters to five "gray market" companies that were taking advantage of drug shortages to charge exorbitant prices for drugs used to treat cancer and other life-threatening conditions. These companies' questionable business practices put patients at risk and cost the United States health care system hundreds of millions of dollars each year.

During drug shortages, hospitals are sometimes unable to buy drugs from their normal trading partners, usually one of the three large national "primary" distributors, AmerisourceBergen, Cardinal Health, or McKesson. At the same time, hospitals are deluged by sales solicitations from gray market companies offering to sell the shortage drugs for prices that are often hundreds of times higher than the prices they normally pay.

The five companies were aggressively marketing five prescription drugs to hospitals that were at the time in short-supply, according to the FDA. Four of the drugs are used to treat various forms of cancer, and one is used to treat seizures during pregnancy. The letters asked the companies where they had obtained the short-supply drugs they were offering for sale and how much they were charging hospitals for the drugs.

In December 2011, Senator John D. Rockefeller IV, Chairman of the Senate Committee on Commerce, Science, and Transportation, and Senator Tom Harkin, Chairman of the Senate Health, Education, Labor, and Pensions Committee, joined Ranking Member Cummings in the investigation. Since that time, the three Members of Congress have requested information from more than 50 prescription drug industry experts, regulators, and stakeholders about how short-supply prescription drugs are distributed, marketed, and sold.

A key source of information in the investigation has been "drug pedigree" documents, which record the distribution route a drug has traveled since it left the manufacturer. Many businesses that distribute drugs in the United States are

required, either by state or federal laws, to provide these pedigrees to their customers.

Congressional investigators carefully studied 300 of these "paper pedigrees," which list the names of all parties that purportedly took possession of the drug and the dates of their possession. The 300 pedigrees show 125 different companies that were involved in selling short-supply prescription drugs. The Committee used the pedigrees to reconstruct how and when drugs entered gray market distribution chains and contacted companies listed in the pedigrees to collect information regarding the prices for which they purchased and re-sold the drugs. The Committee obtained specific information from the companies listed on 58 of the pedigrees, including the prices for which they purchased and sold the drugs and the dates they possessed them.

The drug "pedigree" documents showed that some short-supply injectable drugs "leak" into longer gray market distribution networks, in which a number of different companies – some doing business as pharmacies and some as distributors – buy and resell the drugs to each other before one of them finally sells the drugs to a hospital or other health care facility. In more than two-thirds (69%) of the 300 drug distribution chains reviewed in the investigation, prescription drugs leaked into the gray market through pharmacies. Instead of dispensing the drugs in accordance with their professional duties, state laws, and the expectations of their trading partners, these pharmacies re-sold the drugs to gray market wholesalers. Some pharmacies sold their entire inventories into the gray market. The wholesalers in turn sold the drugs − usually at significant markups − to other gray market companies.

Gray Market Companies Aggressively Mark Up Drug Prices

As the drugs pass through these gray market distribution chains, they are significantly marked up, sometimes to prices that are hundreds of times higher than the prices that hospitals and other health care providers normally pay. The markups in these chains often bear no relation to the companies' cost of purchasing, shipping, or storing the drugs. Instead, they reflect intent to take advantage of the acute demand for short supply drugs by charging health care providers exorbitant prices. Some companies marked up vials by more than 100%, even if they never took physical custody of the vials or only held them for a short time. The hospital that purchased the drug ended up paying $600 per vial for a drug that a pharmacy had purchased for $7 per vial. Hospitals purchase short-supply drugs at these exorbitant prices because, as one hospital explained, "We have no other choice … We have to take care of our patients." The investigation also found that:

- **"Fake Pharmacies" Acquire Prescription Drugs from Authorized Distributors and then Sell Them Into the Gray Market:** A number of businesses hold pharmacy licenses that do not dispense drugs, but

instead appear to operate for the sole purpose of acquiring short-supply drugs that can be sold into the gray market.

- **"Drug Brokers" Recruit Pharmacies to Purchase Drugs for the Gray Market.**
- **Gray Market Business Practices Are Widespread:** Pedigree and price information collected for five different short-supply injectable drugs, documenting the activities of 125 different companies, showed similar patterns of leakage and aggressive gray market price markups. For all five drugs, units normally costing $10 to $20 were regularly marked up to prices of $200 or more while they traveled through the gray market.
- **Gray Market Drugs Are Marked Up as They Quickly Pass from Owner to Owner.** On average, the prescription drugs examined in the investigation were owned by three to four different gray market businesses before being sold to a hospital; most of the drugs traveled through the gray market in five days or less.
- **Gray Market Companies Sometimes Charge Hospitals Significantly Different Prices for the Same Drug Product on the Same Day.**

The Appearance of Gray Market Companies

As a growing number of sterile injectable drugs went into short supply in 2010 and 2011, hospitals around the country began receiving increasing numbers of telephone, fax, and e-mail solicitations from "gray market" drug companies. These companies claimed to have supplies of short-supply drugs that the hospitals could not obtain through their normal distribution channels. The companies' offers generally mentioned the fact that the drugs were in short supply and often suggested that their supplies were very limited.

The gray market companies appeared to be taking advantage of supply shortages to sell the drugs at prices much higher than hospitals paid their normal suppliers. An analysis by the Premier Healthcare Alliance of 636 solicitations made to hospitals in early 2011 found that gray market companies were selling short-supply drugs at prices that were on average 650% higher than the prices hospitals paid for the drugs through their group purchasing agreements. In some cases, companies were selling the drugs at markups as high as 3,000% to 4,000% over their typical contract prices. In addition, some hospital pharmacists believe that gray market wholesalers contact them to learn which drugs the hospitals are having trouble acquiring so that the gray market wholesalers can quickly attempt to buy quantities of those drugs.

When the Institute for Safe Medication Practices (ISMP) surveyed a large group of hospitals in July and August 2011, it received hundreds of comments complaining about the gray market solicitations and asking "why hospitals can't get these products, but the 'scalpers' can." Hospital pharmacists also "reported feeling pressured by physicians and hospital administrators to purchase medications from the gray market."

Choosing between having no supply of a drug or purchasing the drug at an exorbitant price from an unknown gray market company raised difficult ethical and business questions for hospitals. Many hospitals and other stakeholders expressed concern about the safety of drugs purchased from gray market companies because they did not understand how gray market vendors obtain short-supply prescription drugs. Hospitals do not know where the drugs come from or if they were stored properly.

How Drug Distribution Chains Typically Work

A typical drug distribution chain has three elements: (1) a manufacturer, which creates and sells a prescription drug to (2) a wholesale distributor, which then sells the drug to (3) a hospital or pharmacy, which dispenses it to patients. In some cases, additional authorized parties might be involved in these chains. Drug manufacturers sometimes sell their products to "repackagers," before the drugs are distributed. In addition, large "primary" distributors sometimes sell drugs to "secondary" distributors, which then sell the drugs to pharmacies or hospitals. Such sales to secondary distributors comprise only a small percentage of primary distributors' sales.

Distributors that have an ongoing relationships with manufacturers serve as "authorized distributors of record" (ADR) for the manufacturers. About 85% of all revenues in the wholesale market are generated by three national distributors −AmerisourceBergen, Cardinal Health, and McKesson − that serve as ADRs for many manufacturers.

Distributors that predominantly buy prescription medicines from the manufacturers and predominantly distribute them directly to health care providers such as hospitals and pharmacies are called "primary" distributors. "Secondary" distributors are also sometimes ADRs, and they obtain access to drugs from primary distributors or other sources.

Distributors and pharmacies play distinct roles in the distribution chain and are subject to different regulatory and licensing requirements. Under federal law, distributors have the authority to purchase drugs from manufacturers and deliver them to pharmacies, hospitals, and other parties that are not patients. Pharmacies are the end point of the chain, responsible for dispensing the drug in a manner that is consistent with the appropriate treatment of a patient.

In addition to the obligations that come with their licenses as distributors or pharmacies, companies involved in drug distribution chains often also have contractual obligations to their trading partners. Most large distributors purchase drugs from manufacturers pursuant to ADR agreements, which sometimes restrict the distributors' freedom to buy and sell the drugs. The drug manufacturer Hospira, for example, requires its ADRs to commit that "they will

purchase Hospira products directly from Hospira, and only sell Hospira products to end users of our products."

Primary wholesale distributors commonly place similar "own use" restrictions on their customers. For example, one of the primary wholesale distributors requires most of its customers that hold themselves out as "Final Dispensers," such as pharmacies, to certify "that they do not and will not redistribute prescription pharmaceuticals purchased from [that primary wholesale distributor] into the Secondary Market." The same primary wholesale distributor also requires its secondary wholesaler customers to sell to "Final Dispensers" the pharmaceutical products they purchase from that primary wholesale distributor. Another primary wholesale distributor typically requires its final dispenser customers to agree to use purchased products for their "own use" and its secondary wholesaler customers to agree to sell purchased products only to final dispensers.

Ensuring that drugs pass through as few hands as possible on their way to patients helps to ensure the integrity and safety of the drug supply chain. According to the FDA, counterfeit drugs are most likely to be introduced as part of a drug supply chain involving multiple wholesalers.

Detailed Findings of Senate Report

1. Significant Markups Throughout Gray Market Distribution Chains. The Committee found that inflated prices were often the result of unnecessarily long distribution chains, diverted into longer "gray market" distribution networks that include significant markups at almost every level, often hundreds of times higher than the prices the hospitals and other health care providers normally paid for them.

2. Similar Results Found for All Five Shortage Drugs Examined. The pedigree and price information that was collected on the five sterile injectable drugs that were the subject of this investigation show a similar pattern.

3. Additional Information on Gray Market Chains. Some of the most significant results of this analysis were the following:

- In more than half of the transactions, prices for the drugs increased by $200 per unit or more while traveling through the gray market. In six chains, the price increase was $500 or more per unit. The largest increase was $975 per unit.
- On average, drugs traveling through these gray market chains were owned by three to four separate business entities before reaching the hospital or provider that administered the drugs to a patient.
- Most of the drugs traveling through the gray market (60.8%) were sold to hospitals within five days or less after they entered the gray market.55 In

13 chains, the drugs remained in the hands of gray market companies longer than 10 days.

The hospitals that purchased short-supply drugs through the 300 gray market chains staff reviewed include a range of small and large hospitals, urban and rural hospitals, for- profit hospitals, and military, veteran, and other nonprofit hospitals located in all regions of the United States. To estimate the financial impact that gray market purchases have on hospitals, congressional investigators compared actual gray market prices for one form of each of the five drugs reviewed to hospitals' contract price for the same drug product. The per-unit costs in the gray market were dramatically higher than the hospitals would have incurred to purchase the same drugs from their primary wholesale distributors:

Analysis revealed that hospitals overspent nearly $750,000 on over 2,100 units of the five prescription drugs examined as a result of purchasing the drugs from the gray market instead of their normal distributors. The more than 2,100 units included in this analysis are just a fraction of the total number of drug units that were sold in the 300 gray market chains.

How Drugs Enter the Gray Market

1. Drugs Entering Gray Market Primarily Through Pharmacies

2. Some Pharmacies Selling Their Entire Inventories into Gray Market. Evidence that some pharmacies are selling short-supply injectable drugs to gray market wholesalers suggests that these pharmacies are not complying with their states' pharmacy laws that limit re-sales. Some states allow pharmacies to re-sell portions of their inventories in emergency circumstances, while other states permit up to 5% of pharmacies' annual sales to come from re-selling their drugs. The parameters of these exceptions rules vary from state to state. Some states' rules appear to be intended to resolve local supply problems by allowing pharmacies to sell drugs to each other, while other states' rules may permit pharmacies to re-sell their drugs to wholesalers.

Documents obtained during the investigation indicate that some pharmacies are clearly exceeding these limited re-sale exceptions.

3. Using Pharmacies as Purchasing Agents for Shortage Drugs. Documents obtained during the investigation indicate that wholesalers and independent brokers often approached pharmacies and convinced them to purchase shortage drugs on their behalf, promising significant profits. Twenty-one of the 25 pharmacies that responded to requests for information about their purchases and sales of shortage drugs stated that wholesalers or brokers representing wholesalers had asked them to purchase shortage drugs for them.

Documents obtained during the investigation also reveal that brokers and consultants monitor the release of new drug shipments from manufacturers and their distributors. For example, on January 20, 2012, one broker sent an e-mail indicating that a new batch of metoprolol had been released, and asked various pharmacies to buy up the shortage drug, "we just [sic] found some it's been a release find it get sale it [sic]."

Metoprolol is a drug used to improve survival after a heart attack and in the treatment of heart failure. Wholesalers operating in the gray market purchased a significant portion of prescription drugs through pharmacies.

4. Establishing Fake Pharmacies. Documents obtained during the investigation identified numerous entities that appear to have established "fake pharmacies" to gain greater access to shortage drugs. After obtaining these drugs, the "pharmacies" typically did not dispense the drugs to patients pursuant to their pharmacy licenses, but instead sold them to wholesalers they also owned or in which they had interests.

Gray market drug distributors sometimes cite shipping costs as one of the reasons they mark up the per unit price of the drugs they sell. But in many transactions examined in the investigation, the gray market companies billed shipping as a separate line item cost on their invoices. The shipping costs varied, but generally were less than $100 per invoice. In some transactions, the gray market companies never took physical possession of the drugs and instead arranged for drugs to be "drop shipped," directly from the company from which they purchased the drugs, to the customer to which they sold them.

Attachment 6

Title 16. Board of Pharmacy
Second Modified Text

Proposal to Add a New Article 5.5 and Article Title, and Add Sections 1747 and 1747.1 and Section Titles to Article 5.5 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

Article 5.5. Pedigree Requirements.

1747. Unique Identification Number.

For the purposes of Section 4034 of the Business and Professions Code, the "unique identification number" that is to be established and applied to the smallest package or immediate container *as defined in subdivision (d) of Section 4034* by the manufacturer or repackager shall conform to requirements for Standardized Numerical Identifiers (SNIs) set forth in a March 2010 publication by the U.S. Food and Drug Administration (FDA) titled "Guidance for Industry, Standards for Securing the Drug Supply Chain – Standardized Numerical Identification for Prescription Drug Packages," (FDA'S Guidance Document), hereby incorporated by reference. As stated therein, an SNI consists of a serialized National Drug Code (NDC) product identifier combined with a unique numeric or alphanumeric serial number of no more than twenty (20) digits or characters. For dangerous drugs for which no NDC product identifier is assigned or is in use, an equivalent serialized product identifier may be used in place of the NDC consistent with the FDA's Guidance Document. This number shall be combined with a unique numeric or alphanumeric serial number that is not more than 20 digits or characters in length to establish the unique identification number.

This regulation shall become operative on January 1, 2015.

Note: Authority cited: Sections 4005, 4034, and 4163.2, Business and Professions Code. Reference: Sections 4034, 4034.1, 4163, 4163.1, 4163.2, 4163.4, 4163.5, Business and Professions Code.

1747.1. Specification of Pedigreed Dangerous Drugs; Specification of Existing Stock

(a)(1) To comply with Business and Professions Code section 4163.5, each manufacturer of a dangerous drug distributed in California shall submit to the board~~, by December 1, 2014, but~~ no later than December 31, 2014, a declaration signed under penalty of perjury by an

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Changes to the originally proposed language (first modified text) are shown as follows:
Deleted text is shown by double strike-through, thus: ~~deleted language~~.
New or added text is shown by double underline, thus: added language
Changes made to the Second Modified Text are shown as follows:
Deleted text is shown by double strike-through italics, thus: *~~deleted language~~*.
New or added text is shown by double underline italics, thus: *added language*.

31 owner, officer, or employee with authority to bind the manufacturer, containing the
32 following:

33   (A) A list and quantity of dangerous drugs by name and product package (SKU) type
34 representing at least fifty (50) percent of the manufacturer's total that are ready for initial
35 implementation of the serialized electronic pedigree requirements as of January 1, 2015;

36   (B) A statement identifying which one of the following methods was used to measure
37 the percentage of drugs ready to be serialized: (i) unit volume, (ii) product package (SKU)
38 type, or (iii) drug product family;

39   (C) A statement describing the calculation(s) used to arrive at the percentage figure of
40 dangerous drugs ready for serialized pedigree requirements;

41   (D) A list and quantity of dangerous drugs by name and product package (SKU) type that
42 are in the remaining percentage not yet ready to be serialized or subject to pedigree
43 requirements; and,

44   (E) a statement specifying the technology employed to meet the pedigree requirements,
45 including but not limited to any platform(s), vendor(s), hardware, software, and
46 communication technologies deployed.

47   (2) To comply with Business and Professions Code section 4163.5, each manufacturer of a
48 dangerous drug distributed in California shall also submit to the board~~, by December 1, 2015,~~
49 ~~but~~ no later than December 31, 2015, a declaration signed under penalty of perjury by an
50 owner, officer, or employee with authority to bind the manufacturer, containing the
51 following:

52   (A) A list and quantity of its remaining dangerous drugs by name and product package
53 (SKU) type that are ready for implementation of serialized electronic pedigree requirements
54 as of January 1, 2016.

55   (B) A statement identifying which one of the following methods was used to measure
56 the final percentage of drugs to be serialized: (i) unit volume, (ii) product package (SKU)
57 type, or (iii) drug product family;

58   (C) A statement describing the calculation(s) used to arrive at the final percentage
59 figure; and,

60   (D) A statement specifying the technology employed to meet the pedigree
61   requirements, including but not limited to any platform(s), vendor(s), hardware, software,
62   and communication technologies deployed.

63   (3) Any failure to submit to the board a declaration compliant with subdivision (a)(1) by
64   December 31, 2014, any failure to submit to the board a declaration compliant with
65   subdivision (a)(2) by December 31, 2015, or any failure to re-submit either declaration to the
66   board in fully compliant form within ten (10) days after notice of deficiency by the board,
67   shall constitute a violation of the Pharmacy Law.

68   (b) For the purposes of Business and Professions Code sections 4163.2 and 4163.4, any
69   manufacturer, wholesaler or repackager seeking to designate dangerous drugs it possesses,
70   owns, or controls that are not subject to the serialized electronic pedigree requirements,
71   shall submit to the Board, by no later than ~~August 1, 2016,~~ July 31, 2016, a declaration signed
72   under penalty of perjury by an owner, officer, or employee with authority to bind the
73   manufacturer, wholesaler or repackager, containing the following:

74   (1) a list and quantity of dangerous drugs by name, product package (SKU) type and
75   National Drug Code (NDC) product identifier in the possession, ownership, or control of the
76   manufacturer, wholesaler or repackager that were acquired prior to July 1, 2016;

77   (2) a statement that specifies the means and source of acquisition; and,

78   (3) a statement that specifies the anticipated means of any subsequent distribution or
79   disposition.

80   (c) For the purposes of Business and Professions Code sections 4163.2 and 4163.4, any
81   pharmacy or pharmacy warehouse seeking to designate dangerous drugs it possesses,
82   owns, or controls that are not subject to the serialized electronic pedigree requirements,
83   shall submit to the Board, by no later than ~~August 1, 2017,~~ July 31, 2017, a declaration signed
84   under penalty of perjury by an owner, officer, or employee with authority to bind the
85   pharmacy or pharmacy warehouse, containing the following:

86   (1) A list and quantity of dangerous drugs by name, product package (SKU) type and
87   National Drug Code (NDC) product identifier in the possession, ownership, or control of the
88   pharmacy or pharmacy warehouse that were acquired prior to July 1, 2017;

89   (2) A statement that specifies the means and source of acquisition; and,

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Changes to the originally proposed language (first modified text) are shown as follows:
    Deleted text is shown by double strike-through, thus: ~~deleted language~~.
    New or added text is shown by double underline, thus: added language
Changes made to the Second Modified Text are shown as follows:
    Deleted text is shown by double strike-through italics, thus: *~~deleted language~~*.
    New or added text is shown by double underline italics, thus: *added language*.

90   (3) a statement that specifies the anticipated means of any subsequent distribution or
91   disposition.

92   (d) The Board or its designee shall have sole discretion to determine whether any of the
93   declarations submitted pursuant to this Section are compliant, and to reject and require
94   re-submission of any non-compliant declaration(s) until determined to be fully compliant.

95   Note: Authority cited: Sections 4005, 4034, 4163, 4163.2 and 4163.5, Business and
96   Professions Code. Reference: Sections 4034, 4034.1, 4163, 4163.1, 4163.2, 4163.4, 4163.5,
97   Business and Professions Code.

Attachment 7

Certification

(a) For the purposes of Business and Professions Code section 4034, and the delivery and receipt of electronic pedigrees, "certification" shall refer to the process by which each participant in the supply chain confirms and attests to the accuracy of electronic pedigrees transmitted or received in conjunction with delivery, transfer, receipt, or acceptance of corresponding dangerous drugs.

(b) Prior to or contemporaneous with any delivery or other transfer of a dangerous drug pursuant to a transaction requiring transmission and receipt of an electronic pedigree, the delivering or transferring party (hereinafter, the "source") shall transmit to the buying, receiving, or accepting party (hereinafter, the "recipient") via a secured electronic transmission, the electronic pedigree corresponding to the dangerous drug being delivered or transferred, including every change of ownership of the dangerous drug from its initial manufacture through to the transaction between source and recipient, tracked at the smallest package or immediate container as defined in section 4034, subdivision (d). The electronic pedigree transmitted by the source to the recipient shall include, as to each such individual unit, at least the following:

(1) The name and principal address of the source, and the federal or state registration and/or license number held by the source that permits transfer from the source to the recipient. If more than one registration or license held by the source would permit the transfer, then the source may elect to include one or more than one of the eligible numbers.

(2) The trade or generic name of the dangerous drug, the quantity of the dangerous drug, its dosage form and strength, the date of the transaction, the sales invoice number or, if the sales invoice number is not immediately available, a customer-specific shipping reference number linked to the sales invoice number, the container size, the number of containers, the expiration dates, and the lot numbers.

(3) For each owner of the dangerous drug prior to and including the source and the recipient, the business name, address, and federal or state registration and/or license number(s) permitting sale or transfer, and the dangerous drug shipping information, including the name and address of each person certifying delivery or receipt of the dangerous drug.

(4) A certification under penalty of perjury from a responsible party of the source that the information contained in the pedigree is true and accurate.

(5) The unique identification number affixed to the smallest package or immediate container.

The electronic pedigree provided by the source to the recipient shall include a digital signature by a responsible party for the source that prevents any alteration, tampering, or other change to the pedigree, and that guarantees that the data is immutable and non-repudiable by the source.

The certification under penalty of perjury by a responsible party for the source shall attest that, to the best of the ability of the responsible party to know or determine, the information contained in the pedigree is true and accurate. By so attesting, the responsible party confirms that the source has verified the prior transaction history and corresponding certifications for the dangerous drug to the best of its ability, that there is nothing in the prior transaction history that raises suspicion, and that the information in the pedigree corresponds to the dangerous drug being transferred.

(c) Prior to or contemporaneous with receiving a delivery or other transfer of a dangerous drug pursuant to a transaction requiring the transmission and receipt of an electronic pedigree, the recipient shall receive an electronic pedigree from the source that corresponds to the dangerous drug being delivered or transferred. The recipient shall certify receipt of the dangerous drug by verifying the prior transaction history and corresponding certifications for the dangerous drug to the best of its ability, confirming there is nothing in the transaction history that raises suspicion, verifying correspondence between the pedigree data and the dangerous drug received, and by including in the pedigree a digital signature by a responsible party for the recipient that prevents any alteration, tampering, or other change to the pedigree and that guarantees that the data is immutable and non-repudiable by the recipient.

Inference

(a) Pursuant to Business and Professions Code sections 4034 and 4163.3, participants in the distribution chain for dangerous drugs, including manufacturers, wholesalers, or pharmacies furnishing, administering, or dispensing dangerous drugs, shall distribute and receive electronic pedigrees, and verify and validate the delivery and receipt of dangerous drugs against those pedigrees at the unit level, except where the board by regulation defines circumstances under which participants in the distribution chain may infer the contents of a case, pallet, or other aggregate of individual units, packages, or containers of dangerous drugs, from a unique identifier associated with the case, pallet, or other aggregate, without opening each case, pallet, or other aggregate or otherwise individually validating each unit. This regulation defines the limited circumstances under which such an inference will be acceptable.

(b) For the purposes of this section, to "infer" or to rely on an "inference" means that a supply chain participant, in reliance on electronic pedigree information received from a trusted trading partner which provides hierarchical relationships between those unique identifiers affixed to the smallest packages or immediate containers and those unique identifiers affixed to the aggregate container (a case or pallet) into which the smallest packages or immediate containers are placed for purposes of distribution, substitutes scan or review of the unique identifier affixed to the aggregate container for a scan or review of the unique identifiers affixed to the smallest packages or immediate containers contained therein, for purposes of certifying delivery or receipt. The supply chain participant then "infers" that the smallest packages or immediate containers within the aggregate container are what they are expected to be, based on the hierarchical pedigree information, and pairs expected shipments and receipts with the actual physical individual units without opening the sealed aggregate container and scanning or reviewing its contents.

(c) Recipients in the supply chain may infer the smallest package or immediate container contents of a sealed case bearing the original, unbroken, seal or tape affixed by the manufacturer, without breaking the seal, thereby relying on the unique identifier affixed to the sealed case and the inference that hierarchical data relationships between the case identifier and the individual unit identifiers as stated in the electronic pedigree have been correctly stated and remain true, and accurately describe the case contents, only under the following circumstances:

   (1) Where the source has transmitted to the recipient prior to receipt of the sealed case a certified electronic pedigree record establishing a hierarchical data relationship between the unique identifier affixed to the sealed case and the individual unit identifiers;

   (2) Where the electronic pedigree data was received via a secured electronic transmission, and includes a digital signature by a responsible party for the source that prevents any alteration, tampering, or other change to the pedigree and that guarantees that the data is immutable and non-repudiable by the source;

   (3) Where the case is and has remained sealed with the original, unbroken, seal or tape affixed by the manufacturer, and shows no signs of tampering or being opened;

   (4) Where the sealed case is homogenous, i.e., contains only one dangerous drug product, and contains no more than forty-eight (48) units of that dangerous drug product;

(5) Where the sealed case and accompanying pedigree data were received from a trusted trading partner. For the purposes of this section, a "trusted trading partner" is a source:
  a. with which the recipient has an established relationship and existing contract;
  b. for which the recipient has verified the federal or state registration and/or license number held by the source that permits transfer from the source to the recipient;
  c. with which the recipient has established agreed and mutually-executed standard operating procedures (SOPs) that define, at minimum, the requirements to gain and maintain "trusted trading partner" status, the circumstances under which an inference will be deployed, the limitations on that deployment, the sampling plan for sampling sealed, homogenous cases for continued compliance, and the means and time limits for remediation of any data or product discrepancies discovered;
  d. from which the recipient has received at least five (5) shipments of sealed cases containing homogenous products, has physically verified the individual unit contents, and certified 100% accuracy of the electronic pedigree data received – detailed records of this verification process and the results of the inspections shall be kept and made available for inspection upon request by an authorized officer of the law or by an authorized representative of the board;
  e. for which there has been no prior need for manual intervention with regard to any sealed cases previously received, other than individual unit identifier scans;
  f. for which there is written approval by the recipient's compliance manager, signed under penalty of perjury and maintained for review by the board for as long as the status persists, of "trusted trading partner" status for the source; and
  g. with which there is a written agreement in place specifying the means and time limits of remediation of, and the apportionment of liability for, any discrepancies discovered in either the electronic pedigree data or the drug products received;

(6) Where the source and recipient have agreed and mutually-executed standard operating procedures (SOPs) that define, at minimum, the requirements to gain and maintain "trusted trading partner" status, the circumstances under which an inference will be deployed, the limitations on that deployment, the sampling plan for sampling sealed, homogenous cases for continued compliance, and the means and time limits for remediation of any data or product discrepancies discovered, and where the source and recipient have a written agreement in place specifying the means and time limits of remediation of, and the apportionment of liability for, any discrepancies discovered in either the electronic pedigree data or the drug products received, either or both of which shall be made immediately available for inspection by an authorized officer of the law or by an authorized representative of the board, upon request;

ADDITIONAL CONCEPTS:

(A) Sampling/audits must be at least at the level of ANSI/ASQZI.4-2008, Special Level S-1 and the single sampling plan for normal inspections;
(B) When sealed case is opened, its entire contents must be immediately scanned;
(C) Any discrepancies discovered in data or products must be remedied within 48 hours;
(D) The pedigree data must indicate that an inference was deployed for the certifications;
(E) Liability must be shared by all parties propagating or relying on the inference.

Inspection

(a) Pursuant to Business and Professions Code sections 4081 and 4105, electronic pedigree records are among the records of manufacture, sale, acquisition, or disposition of dangerous drugs that shall be at all times during business hours open to inspection by authorized officers of the law, that shall be preserved for at least three years from the date of making, and that shall be at all times retained on the licensed premises in a readily retrievable form.

(b) Electronic pedigree records shall be maintained so that the pharmacist-in-charge, the pharmacist on duty if the pharmacist-in-charge is not on duty, or, in the case of a veterinary food-animal drug retailer or wholesaler, the designated representative on duty, shall, at all times during which the licensed premises are open for business, be able to produce a hard copy and electronic copy of the electronic pedigree records.

(c) Upon request by an authorized officer of the law or by an authorized representative of the board, the electronic records shall be made immediately available in electronic format for duplication or download, duplicated or printed into a paper format, or both, as directed.

(d) Each licensed premises shall have available a scanner and terminal that may be used by an authorized officer of the law or by an authorized representative of the board to access electronic pedigree record information regarding the smallest package or immediate container for any dangerous drug by, among other things, scanning the unique identification number affixed to the smallest package or immediate container and accessing the corresponding pedigree.

Attachment 8

Buyer beware of faux pharmaceuticals

MEDICINE

Victoria Colliver

Federal regulators earlier this month discovered another batch in a string of fake versions of Genentech's cancer drug, Avastin.

Last month, a doctor in La Jolla pleaded guilty in federal court to treating patients with unapproved drugs.

Tainted steroids produced by a Massachusetts compounding pharmacy led to a fungal meningitis outbreak in September that killed 45 people and sickened more than 650.

The problem of fake, contaminated or prescription drugs that don't meet proper quality standards may be worse in developing countries, but drug security is clearly a concern here, too.

Even in the United States, medicines change hands many times and the path these drugs take from manufacturer to the pharmacist or doctor is not tracked, making it possible for illegitimate products to infiltrate the supply chain from within or outside U.S. borders.

"As we become more globalized, I think it's reasonable to expect the problem caused by this will only increase," said Dr. Patrick Kelley, director of the Institute of Medicine's Board on Global Health, in introducing a report last week that called for a global effort to beef up drug surveillance and tracking.

Tough to quantify

Quantifying the problem in the United States is difficult, but the trade of adulterated prescription drugs is considered more profitable than that of illicit drugs, like heroin, said the authors of the 360-page report, which was sponsored by the U.S. Food and Drug Administration.

"Many of these fake drugs are the subject of sophisticated criminal networks," said Larry Gostin, professor of health law at Georgetown University, who headed the committee that produced the report.

Expired or adulterated prescription drugs often fall into the hands of unwitting health care providers from a secondary wholesaler offering what appears to be a good deal for the medication, the report said. Frequently, the problem may go undetected unless adverse side effects or deaths occur.

"The consequences of illegitimate drugs are compromised treatment - they may have no therapeutic, active ingredient or it may be of a lower amount. They can be toxic or poisonous. They can harm patients and, in some cases, they can kill," Gostin said.

In some cases, regulators don't need a death or illness to alert them of the problem.

Targeting Avastin

In the case of Avastin, U.S. regulators discovered fake versions of the cancer-fighting drug Avastin. According to the Institute of Medicine, the drugs were given to U.S. patients in 2011 and 2012, but no deaths or illnesses associated with the crime have been reported.

In one incident involving Avastin, the false version contained no trace of the actual drug, which costs $2,500 per vial and is used to treat cancers of the lung, colon, kidney and brain. In another case last year, a fake Turkish version of Avastin, labeled under the Turkish brand name Altuzan, was found in the United States. Authorities would not reveal how the drugs were discovered.

Earlier this month, the FDA warned that additional counterfeit versions of Avastin, also sold under the Turkish brand name, had been distributed by a U.S. company.

"The investigation is still ongoing into whether the medicine actually got to doctors and patients," said Genentech spokesman Ed Lang. He said the company has noticed the increase in reports of fake cancer drugs.

The South San Francisco company, which is owned by Roche, has been working to combat counterfeiting through special packaging and printing techniques.

The company said it also only distributes its products through a defined list of licensed wholesalers and specialty distributors, so any products not purchased through those sources should be considered suspect.

Too complex to solve

No one system or technology will completely resolve the problem because of its complexity.

Fake or substandard drugs appear through a variety of means. In some cases, counterfeiters produce packaging that looks authentic and can only be detected through sophisticated means.

Some substandard drugs are real medications that have been stolen, stored in shoddy conditions and resold. Those medications might have become contaminated or expired, also posing a potential health risk.

Meanwhile, the Institute of Medicine report calls for a variety of potential solutions, such as better ways to authenticate packaging so that regulators may be able to identify and detect counterfeit drugs. This could include better inks, holograms or other security features that could outwit counterfeiters.

The report also calls for improved tracking systems for keeping tabs on every time a drug changes hands. The system, often referred to as an "electronic pedigree," could better secure the supply chain, leaving fewer opportunities for bad drugs to enter the health market.

The United States has no national system to track and trace drugs through its maze of wholesalers and secondary marketers.

State's law delayed

The report's authors singled out California, which in 2004 became the first state to approve an electronic drug-tracking system. But implementation of the law, which will require a unique serial number on bottles and vials, has been delayed numerous times to give manufacturers more time to develop their systems. It is now set to go into effect in 2015.

Virginia Herold, executive director of the California State Board of Pharmacy, welcomed the additional attention the report gives to the issue and said she expects the state's system to become a model for the nation.

"We have got a supply chain we need to shore up," she said. "What our law does is every time a product changes hands, there will be tracking certification."

Turning to technology

Not unexpectedly, a number of companies are jockeying to improve drug authentication and tracking systems.

Bar-coding and wireless radio-frequency identification, or RFID, are some of the technologies being used or considered to better track drugs. Much of the technologies are focused on securing company drug packaging so it is more difficult to counterfeit.

Other technologies and concepts are being tested. For example, TruTag Technologies, which has offices in Oakland, has created an invisible, edible "code" that can be applied to pills so each individual pill can be tracked.

Details embedded

The technology uses a chemical compound called silicon dioxide, or silica, that is embedded with information about the drug - product strength, batch number, expiration date, site of manufacturing. Each pill is coated with the material, which cannot be seen with naked eye.

"There's really no limit on what information you can associate with the code," said TruTag's president, Kent Mansfield. "For counterfeiters, you need a multi-layer approach. RFID and 2D barcodes have their place, but they have their limits."

The state Board of Pharmacy's Herold said these new technologies along with tightened drug tracking laws will help reduce the incidence of fake drugs getting into the supply chain and offer patients a higher level of security.

"People need to be sure their health care providers are getting drugs from appropriate places," she said. "It's the not the supply chain - A to B to C - like you think. It's a mess."

About fake and poor quality drugs

What are falsified or substandard drugs? These are bad drugs that fail to meet proper standards. This includes drugs that are counterfeit, expired, not registered in the country in which they are found, or are not kept in proper conditions. These drugs could contain none of the real drug, have diluted quantities, or have become contaminated or degraded.

How big is the problem? It's unclear because of its covert nature, but a network of security firms from major pharmaceutical companies found fake or substandard drugs in 124 counties in 2011. Organized crime has sophisticated methods that make the problem difficult to detect. Many countries lack resources to track and regulate drugs.

What can be done to combat it? A new report by the Institute of Medicine calls for a global solution to the problem. The report recommends that governments strengthen regulatory systems, create stricter tracking methods, increase enforcement and license only those manufacturers that meet international standards.

To read the Institute of Medicine's report, "Countering the Problem of Falsified and Substandard Drugs," visit http://bit.ly/XAuqYL

Source: Institute of Medicine

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Attachment 9

Board of Pharmacy Enforcement Statistics
Fiscal Year 2012/2013

Workload Statistics	July-Sept	Oct-Dec	Jan-Mar	Apr-June	Total 12/13
Complaints/Investigations					
Received	674	753	651		2078
Closed	585	610	926		2121
4301 letters	40	34	47		121
Pending (at the end of quarter)	2193	2362	2198		2198
Cases Assigned & Pending (by Team) at end of quarter*					
Compliance / Routine Team	819	981	833		833
Drug Diversion/Fraud	380	321	420		420
Probation/PRP	107	98	117		117
Mediation/Enforcement **	243	337	370		370
Criminal Conviction	644	625	458		458
Application Investigations					
Received	220	177	164		561
Closed					
Approved	162	144	34		340
Denied	41	31	39		111
Total ***	283	226	224		733
Pending (at the end of quarter)	235	191	136		136
Letter of Admonishment (LOA) / Citation & Fine					
LOAs Issued	53	19	45		117
Citations Issued	249	284	463		996
Total Fines Collected ****	$831,660.29	$450,459.00	$489,622.15		$1,771,741.44

* This figure include reports submitted to the supervisor and cases with SI awaiting assignment.

** This figure include reports submitted to the citation and fine unit, AG referral, as well as cases assigned to enf. Staff

*** This figure includes withdrawn applications.

****Fines collected (through 3/31/2013 and reports in previous fiscal year.)

Board of Pharmacy Enforcement Statistics
Fiscal Year 2012/2013

Workload Statistics	July-Sept	Oct-Dec	Jan-Mar	Apr-June	Total 12/13
Administrative Cases (by effective date of decision)					
Referred to AG's Office*	144	107	131		382
Accusations Filed	42	38	52		132
Statement of Issues Filed	14	16	17		47
Petitions to Revoke Filed	5	3	2		10
Pending					
Pre-accusation	189	214	267		267
Post Accusation	223	203	228		228
Total*	501	459	557		557
Closed					
Revocation					
Pharmacist	2	1	5		8
Intern Pharmacist	0	0	0		0
Pharmacy Technician	20	26	13		59
Designated Representative	1	0	0		1
Wholesaler	1	0	0		1
Pharmacy	2	3	0		5
Revocation,stayed; suspension/probation					
Pharmacist	2	4	1		7
Intern Pharmacist	0	0	0		0
Pharmacy Technician	0	0	0		0
Designated Representative	0	0	0		0
Wholesaler	0	0	0		0
Pharmacy	0	0	0		0
Revocation,stayed; probation					
Pharmacist	4	3	2		9
Intern Pharmacist	0	0	0		0
Pharmacy Technician	3	7	5		15
Designated Representative	0	0	0		0
Wholesaler	0	0	0		0
Pharmacy	0	1	0		1
Surrender/Voluntary Surrender					
Pharmacist	2	2	0		4
Intern Pharmacist	0	1	0		1
Pharmacy Technician	5	6	2		13
Designated Representative	0	0	0		0
Wholesaler	0	0	1		1
Pharmacy	0	3	1		4

Board of Pharmacy Enforcement Statistics
Fiscal Year 2012/2013

Workload Statistics	July-Sept	Oct-Dec	Jan-Mar	Apr-June	Total 12/13
Public Reproval/Reprimand					
Pharmacist	1	0	0		1
Intern Pharmacist	0	0	0		0
Pharmacy Technician	0	0	0		0
Designated Representative	0	0	0		0
Wholesaler	0	0	0		0
Pharmacy	0	0	0		0
Cost Recovery Requested**	$113,913.52	$257,487.00	$98,451.00		$469,851.52
Cost Recovery Collected**	$149,899.65	$217,472.09	$141,213.29		$508,585.03

Immediate Public Protection Sanctions					
Interim Suspension Order	0	0	0		0
Automatic Suspension / Based on Conviction	0	0	3		3
Penal Code 23 Restriction	0	3	0		3

* This figure includes Citation Appeals

** This figure includes administrative penalties

Probation Statistics

Licenses on Probation					
Pharmacist	127	129	123		123
Intern Pharmacist	4	4	3		3
Pharmacy Technician	49	54	57		57
Designated Representative	2	3	2		2
Pharmacy	26	25	6		6
Wholesaler	4	4	4		4
Probation Office Conferences	21	26	35		82
Probation Site Inspections	67	53	61		181
Successful Completion	7	3	5		15
Probationers Referred to AG for non-compliance	4	3	13		20

As part of probation monitoring, the board requires licensees to appear before the supervising inspector at probation office conferences.

These conferences are used as 1) an orientation to probation and the specific requirements of probation at the onset,

2) to address areas of non-compliance when other efforts such as letters have failed, and 3) when a licensee is scheduled to

end probation.

As of March 31, 2013.

SB 1441 – Program Statistics

Pharmacist Recovery Program (PRP)

Board of Pharmacy	July -Sep	Oct – Dec	Jan-Mar	Apr-Jun	Total 12/13
PRP Self-Referrals	1	2			3
PRP Board Referrals	2	4	1		7
PRP Under Investigation	2	2	1		5
PRP In Lieu Of					
PRP Intakes	5	8	2		15
New Probationers					
Pharmacists	3	4	2		9
Interns					
Technicians	3	7	2		12
Total PRP Participants	71	72	72		N/A
Contracts Reviewed	65	73	67		205
Total Probationers	125	118	119		N/A
Inspections Completed	84	79	61		224
Referrals to Treatment					
Referrals to Treatment	3	5			8
Drug Test Ordered	1175	1223	1265		3663
Drug Tests Conducted	986	987	1068		3041
Relapsed					
Relapsed	2	1	1		4
Major Violation Actions					
Cease Practice/Suspension	1	2	1		4
Termination - PRP	1		2		3
Referral for Discipline	4				4
Exit from PRP or Probation					
Successful Completion	9	6	7		22
Termination - Probation	1	2	1		4
Voluntary Surrender	8	5	10		23
Surrender as a result of PTR			1		1
Public Risk	1		2		3
Non-compliance	19	7	6		32
Other	1	1			2
Number of Patients Harmed					
Drug of Choice at PRP Intake or Probation					
Pharmacists	**July-Sep**	**Oct-Dec**	**Jan-Mar**	**Apr-Jun**	**Total 12/13**
Alcohol	5	4	1		10
Ambien	1	2			3
Opiates		2	1		3
Hydrocodone	1				1
Oxycodone		1			1
Morphine	1				1
Benzodiazepines	2				2
Barbiturates		1			1
Marijuana					
Heroin					
Cocaine	1				1

SB 1441 – Program Statistics

Pharmacist Recovery Program (PRP)

Board of Pharmacy	July -Sep	Oct – Dec	Jan-Mar	Apr-Jun	Total 12/13
Methamphetamine					
Pharmaceutical Amphetamine					
Phentermine					
Methadone					
Zolpidem Tartrate					
Hydromorphone					
Promethazine w/Codeine					
Intern Pharmacists	**July-Sep**	**Oct-Dec**	**Jan-Mar**	**Apr-Jun**	**Total 12/13**
Alcohol					
Opiates					
Hydrocodone					
Oxycodone					
Benzodiazepines					
Barbiturates					
Marijuana					
Heroin					
Cocaine					
Methamphetamine					
Pharmaceutical Amphetamine					
Phentermine					
Methadone					
Zolpidem Tartrate					
Hydromorphone					
Promethazine w/Codeine					
Pharmacy Technicians	**July-Sep**	**Oct-Dec**	**Jan-Mar**	**Apr-Jun**	**Total 12/13**
Alcohol	1	4	1		6
Opiates					
Hydrocodone		1	1		2
Oxycodone		1			1
Benzodiazepines	1				1
Barbiturates					
Marijuana		1			1
Heroin					
Cocaine		1			1
Methamphetamine	1	2			3
Pharmaceutical Amphetamine					
Phentermine					
Methadone					
Zolpidem Tartrate					
Hydromorphone					
Promethazine w/Codeine					
Pharmacist Recovery Program	**July-Sep**	**Oct-Dec**	**Jan-Mar**	**Apr-Jun**	**Total 12/13**
Participant Files Audited					

Drug Of Choice - Data entered from July 2012 to June 2013

Pharmacist

Intern

Technician

1	Alcohol
2	Opiates
3	Hydrocodone
4	Oxycodone
5	Benzodiazepines
6	Barbiturates
7	Marijuana
8	Heroin
9	Cocaine
10	Methamphetamine
11	Pharmaceutical Amphetamine

Printed on 4/15/2013
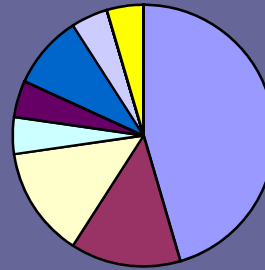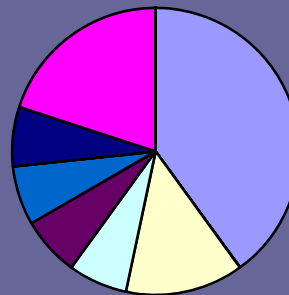
Attachment 10

Strategic Planning: Enforcement

	Success Indicators	Related Performance Measures	Acceptance Parameters		Actual Percentage Green Light Status	Explanation
1A	Complete all desk investigations within 120 days.	[CP, CC, EF, QE, RC]	○	93%	53%	Cases with multiple offenses take longer to investigate. In addition to relying on other agencies to provide documents as well as staff vacancies.
			○	75%		
			● (red)	74%		
1B	Open all complaints within 10 days.	[CP, CC, EF, QE, RC]	○	90%	55%	Staff vacancy in complaint unit prevented the board from opening complaints within 10 days.
			○	76%		
			● (red)	75%		
1C	Review all investigations within 30 days.	[CP, CC, EF, QE, RC]	○	97%	n/a	Under Development
			○	94%		
			○	93%		
1D	Complete all field investigations within 120 days.	[CP, CC, EF, QE, RC]	○	94%	59%	Inspector vacancies and new inspector training prevented inspector staff to complete investigations timely.
			○	75%		
			● (red)	74%		
1E	Close all Board investigations and mediations within 180 days.	[CP, CC, EF, QE, RC]	○	97%	43%	Inspector vacancies and new inspector training prevented inspector staff to complete investigations timely.
			○	94%		
			● (red)	93%		
1F	Issue citations and fines within 30 days.	[CP, CC, EF, QE, RC]	○	96%	48%	Due to the number of cases to be split and issued there was a delay in issuing citations.
			○	92%		
			● (red)	91%		

Strategic Planning: Enforcement

1G	Issue letters of admonishment within 30 days.	[CP, CC, EF, QE, RC]	○ 98% ○ 95% ● 94%	36%	Due to the number of cases to be split and issued there was a delay in issuing letters of admonishments.
1H	Complete all field investigations for cases involving drug abuse within 60 days.	[CP, HE, QE, RC]	○ 90% ○ 80% ○ 70%	n/a	Under Development
1I	Refer all cases to the AG's office within 10 days.	[CP, QE, RC]	○ 97% ○ 82% ● 81%	19%	Due to staff absences and the volume of cases to be referred, cases were not sent over within 10 days or less.
1J	Secure pleadings from AG's office within 90 days after referral.	[CP, QE, RC]	○ 96% ○ 82% ● 81%	46%	The board relies on the deputies from the Attorney Generals Office to forward pleadings within 90 days. Staff workload has prevented follow ups with the AGs Office.
1K	Inspect 100 percent of all licensed facilities once every three years by June 30, 2015.	[CP, QE, RC]	○ 90% ○ 80% ○ 70%	n/a	This section is still under development however the board conducted 472 inspections this quarter.
1L	Review draft pleadings within 30 days.	[CP, QE, RC]	○ 90% ○ 88% ● 87%	13%	Due to the high volume of workload this objective is not currently being met.
1M	Perform quarterly status reports for all referral cases pending.	[CP, QE, RC]	○ 90% ○ 80% ● 70%	2%	Workload with mail votes and board packet preparation did not allow analyst to perform this function.

Strategic Planning: Enforcement

1N	Secure mail votes on all decisions within 30 days of receipt.	[CP, QE, RC]	○ 97% ○ 91% 🔴 90%	57%	Delay in sending and securing votes to and from board members.
1O	Complete petitions to revoke probation cases within 30 days.	[CP, QE, RC]	○ 98% ○ 95% 🔴 94%	0%	High volume of staff workload has prevented the analyst to complete these cases timely.
1P	Quarterly evaluate 5% of the Pharmacist Recovery Program (PRP) participants to ensure the PRP Contractor is in compliance with the contract.	[CP, QE, RC]	○ 98% ○ 95% 🔴 94%	0%	Staff manager training in complaint unit did not allow manager to perform this task.
1Q	Pursue disciplinary action, within 10 days, on a licensee closed a public risk from the Pharmacists Recovery Program.	[CP, QE, RC]	🟢 98% ○ 95% ○ 94%	100%	

1A. Complete all desk investigations within 120 days.
(Recorded as number of cases submitted)
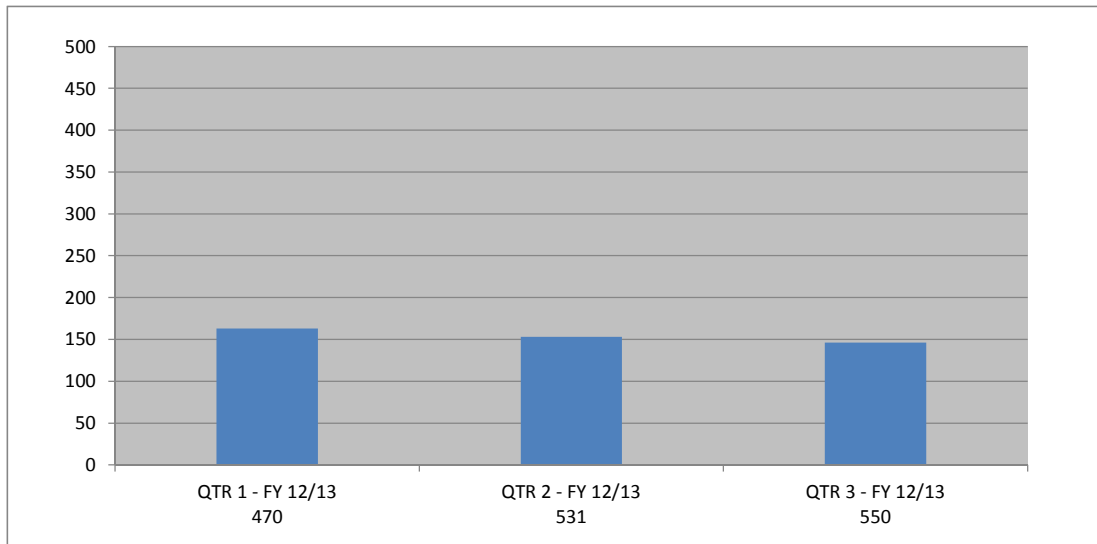
1B. Open all consumer complaints within 10 days.
(Recorded as number of cases opened)
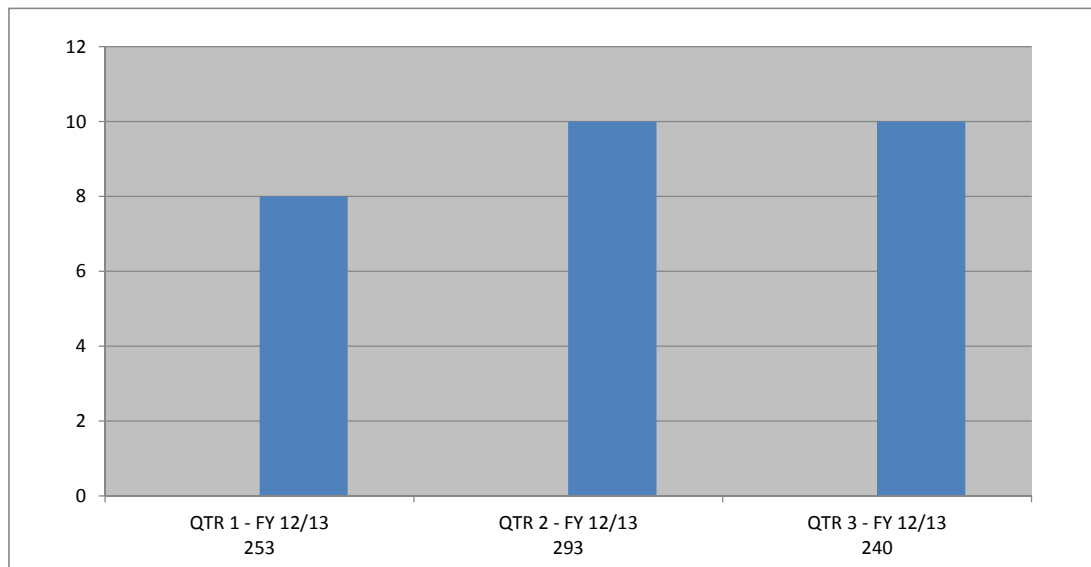
1C. Review all investigations within 30 days.
(Recorded as number of cases reveiwed)
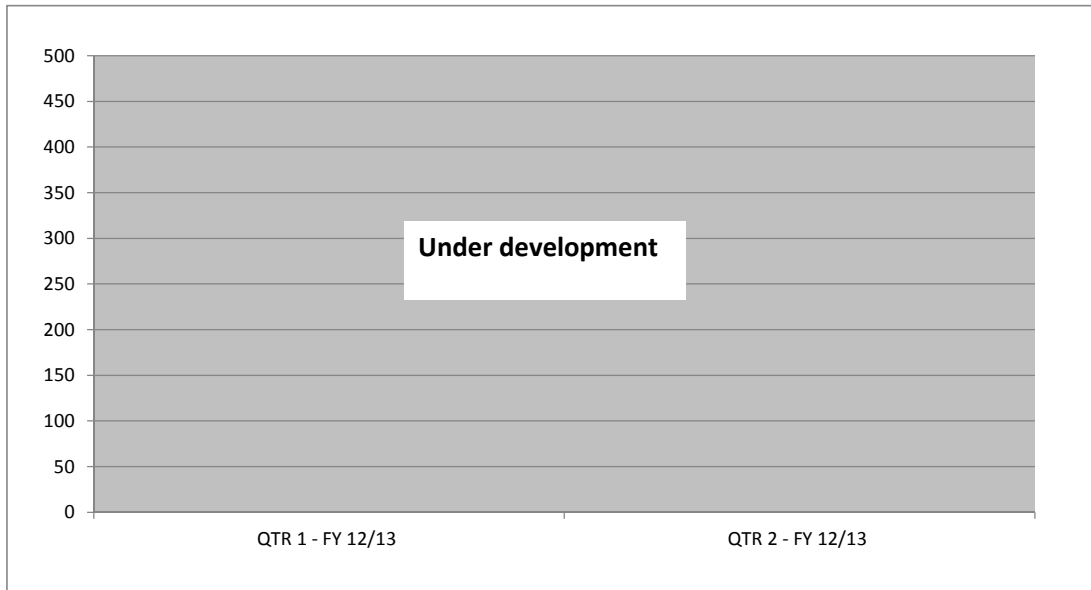
1D. Complete all field investigations within 120 days.
(Recorded as number of cases submitted)
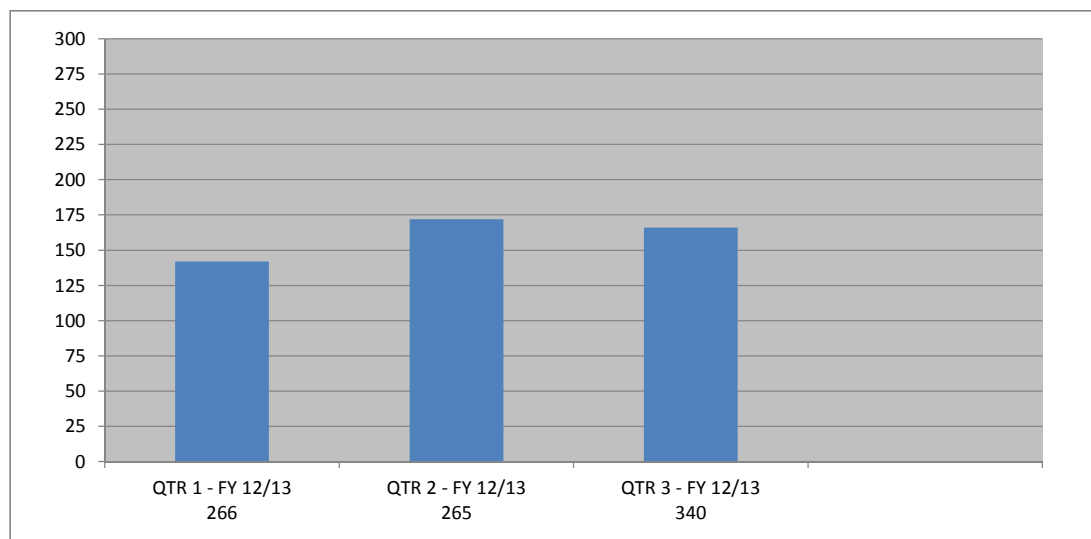
1E. Close all Board investigations and mediations within 180 days.
(Recorded as number of cases closed)

	QTR 1 - FY 12/13 682	QTR 2 - FY 12/13 771	QTR 3 - FY 12/13 1,032
Value	~350	~245	~247
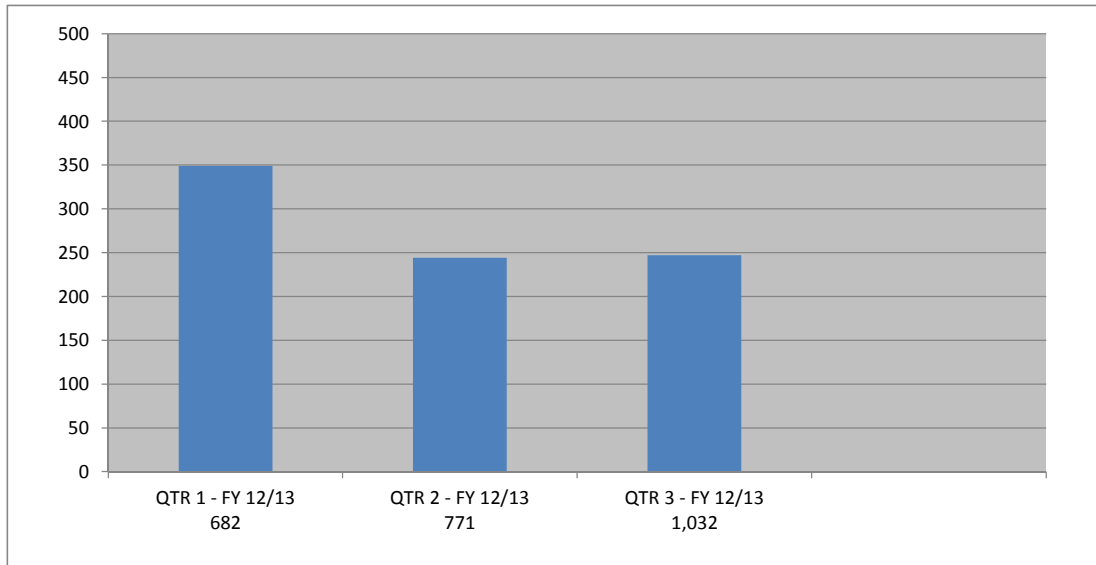
1F. Issue citations and fines within 30 days.
(Recorded as number of citations issued)

	QTR 1 - FY 12/13 246	QTR 2 - FY 12/13 284	QTR 3 - FY 12/13 463
Value	20	23	32
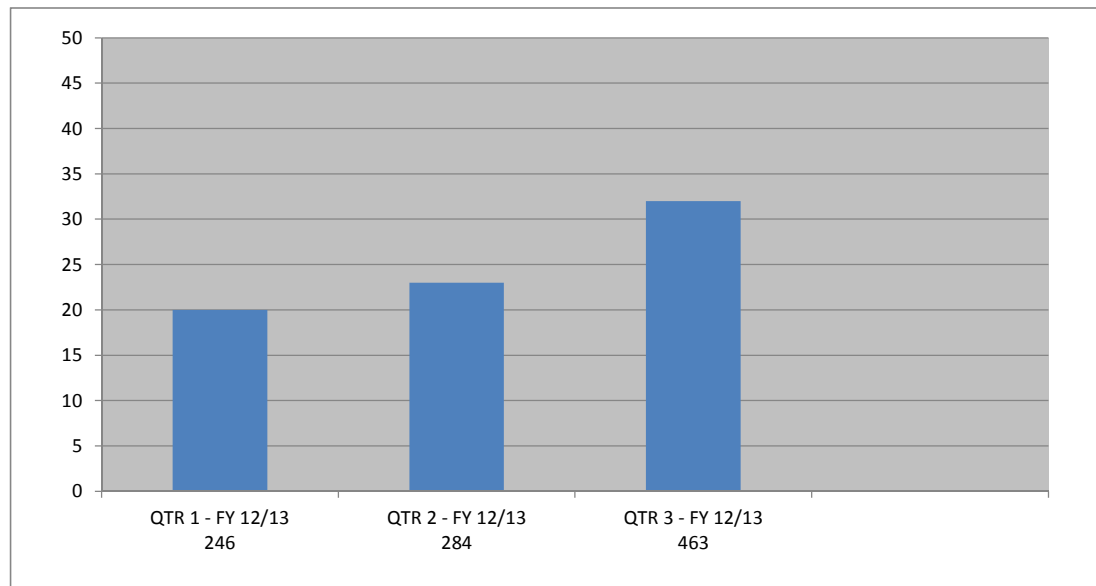
1G. Issue letters of admonishiment within 30 days.
(Recorded as number of letters of admonishment issued)
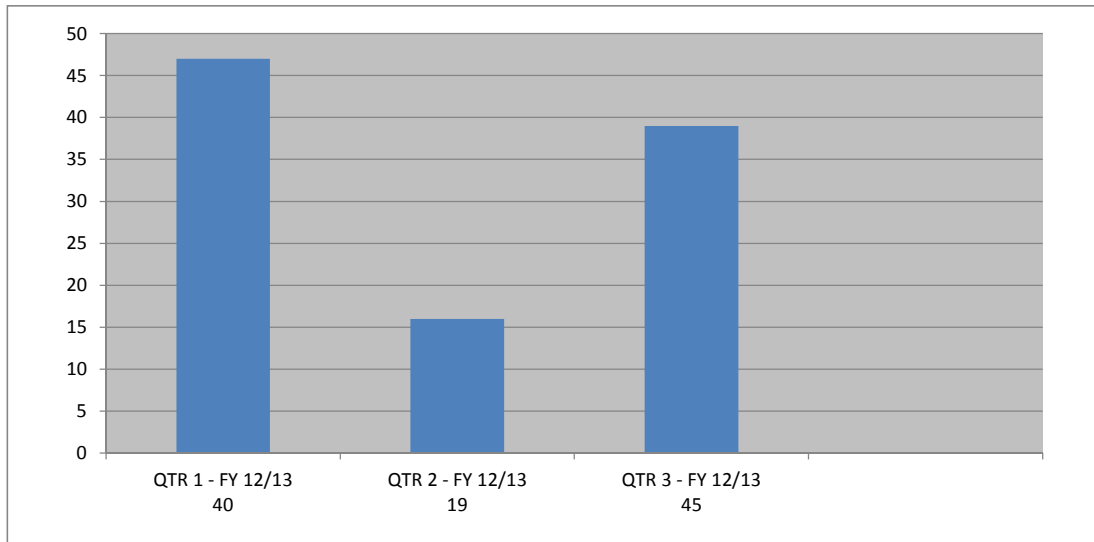
	QTR 1 - FY 12/13	QTR 2 - FY 12/13	QTR 3 - FY 12/13
	40	19	45

1H. Complete all field investigations for cases involving drug abuse within 60 days.

Under development

QTR 1 - FY 12/13	QTR 2 - FY 12/13	QTR 3 - FY 12/13
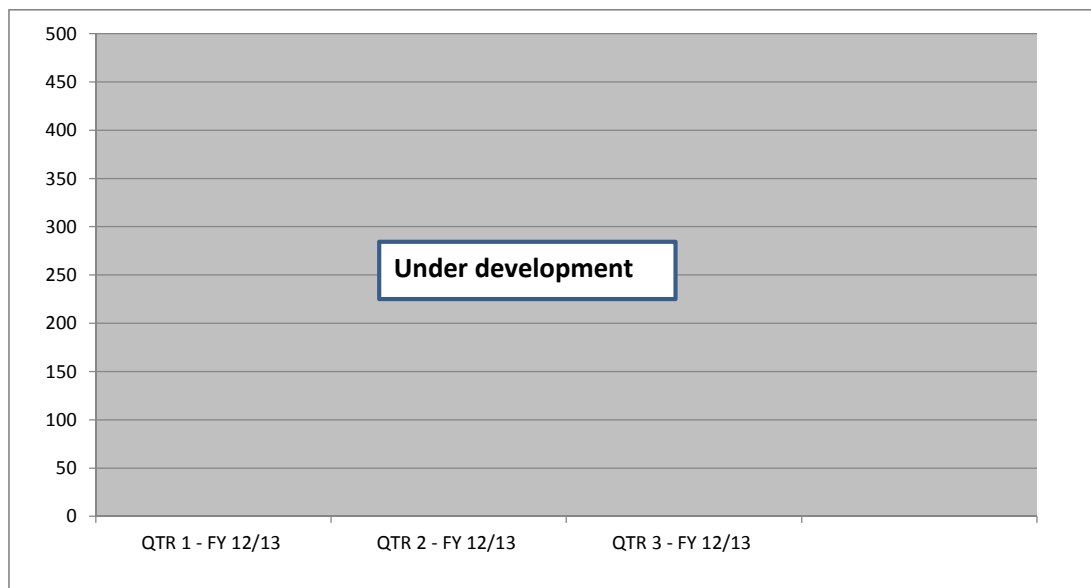
1I. Refer all cases to the AG's Office within 10 days.

(Recorded as number of cases referred)
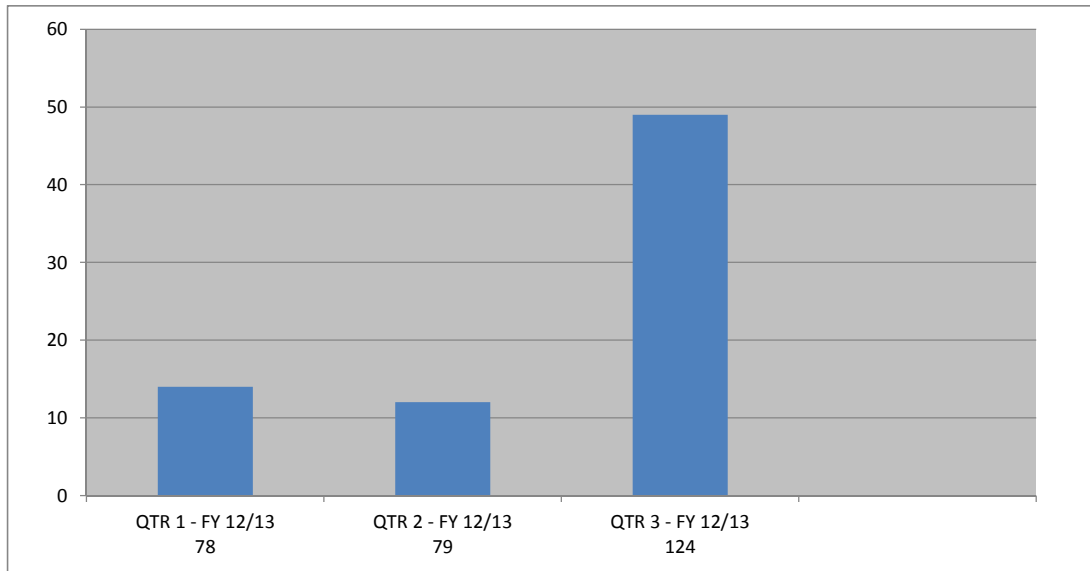
1J. Secure pleadings from AG's Office within 90 days after referral.

(Recorded as number of pleadings received)
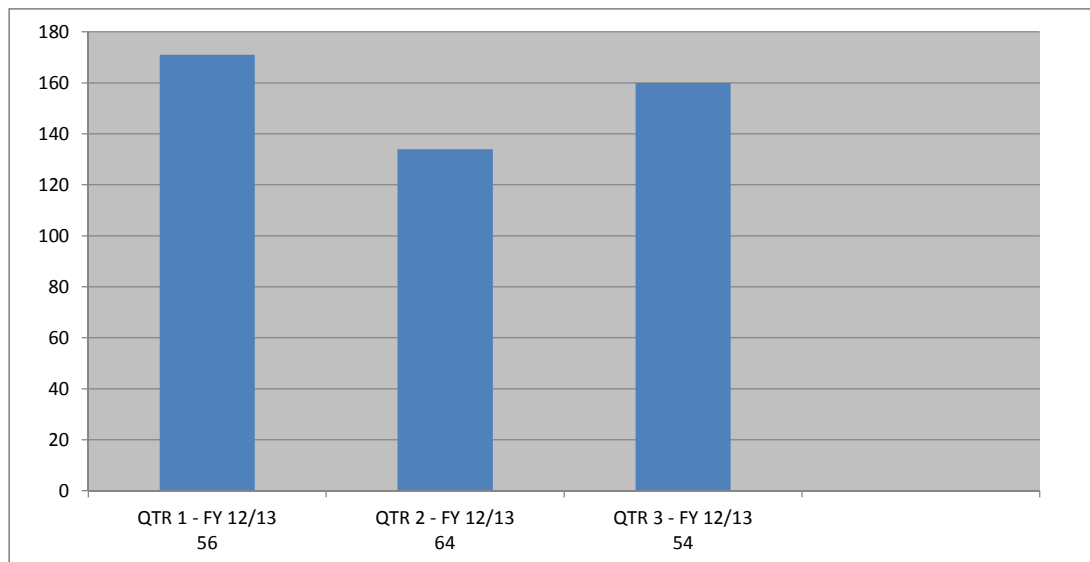
1K. Inspect 100 percent of all licensed facilities once every three years by June 30, 2015.
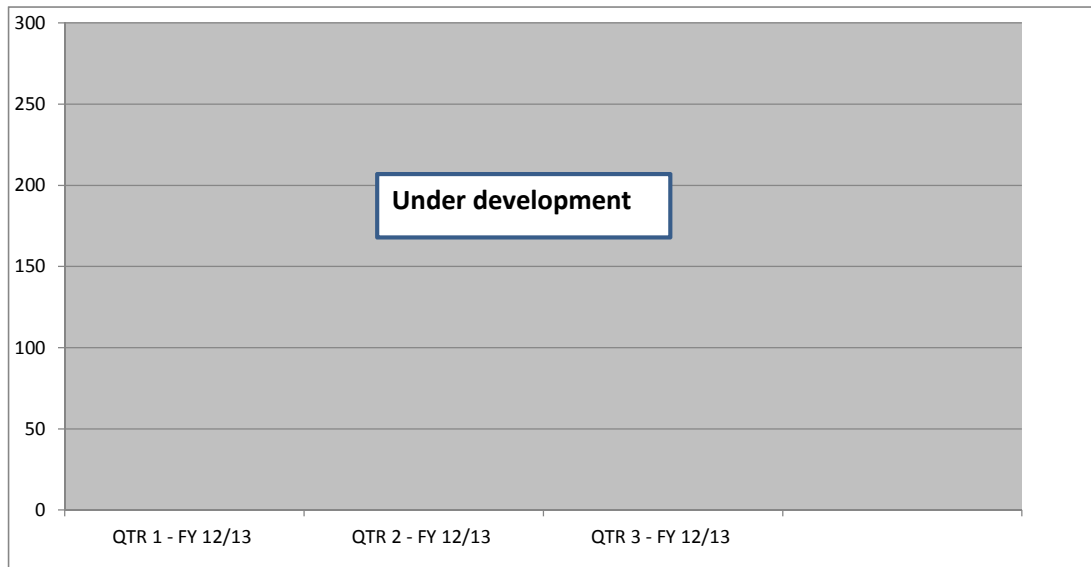
1L. Review draft pleadings within 30 days.
(Recorded as number of pleadings filed)
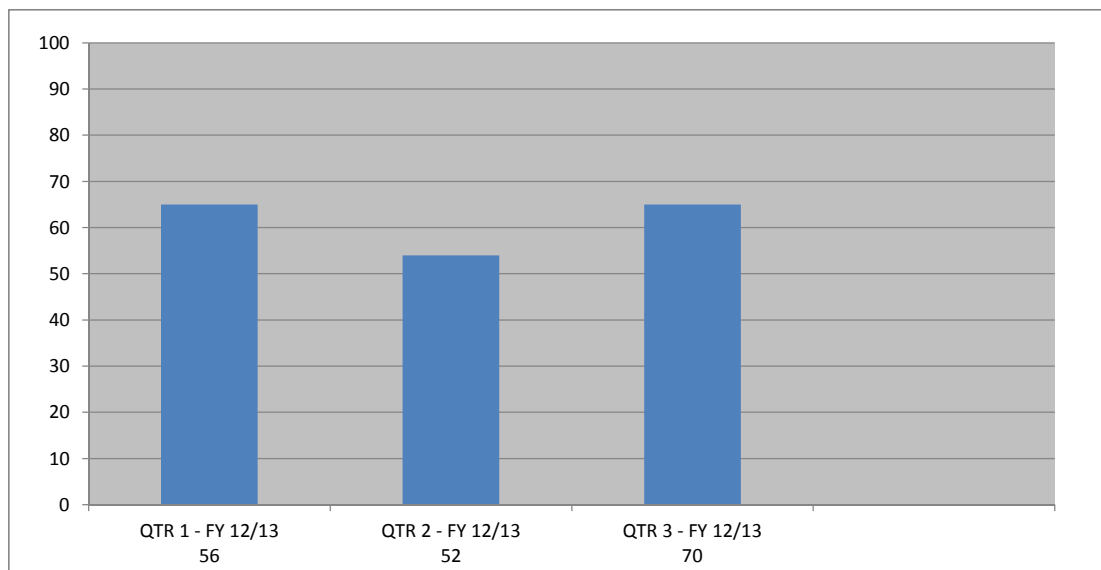
1M. Perform quarterly status reports for all referral cases pending.

(Recorded as number of cases pending over 90 days.

	QTR 1 - FY 12/13	QTR 2 - FY 12/13	QTR 3 - FY 12/13
	0	324	324
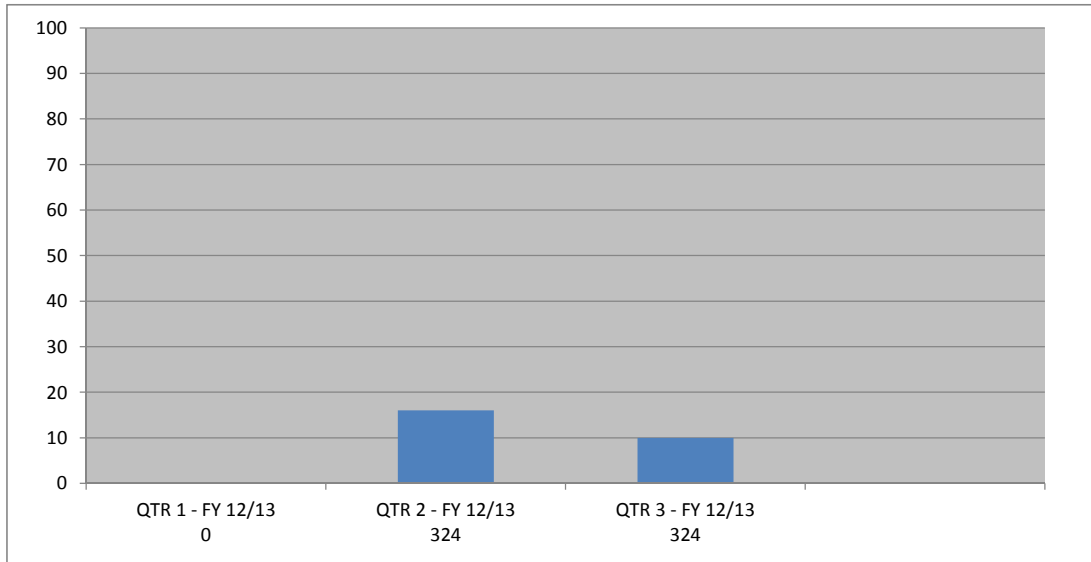
1N. Secure mail votes on all decisions within 30 days of receipt.

(Recorded as number of decisions received for mail vote)

	QTR 1 - FY 12/13	QTR 2 - FY 12/13	QTR 3 - FY 12/13
	65	58	51
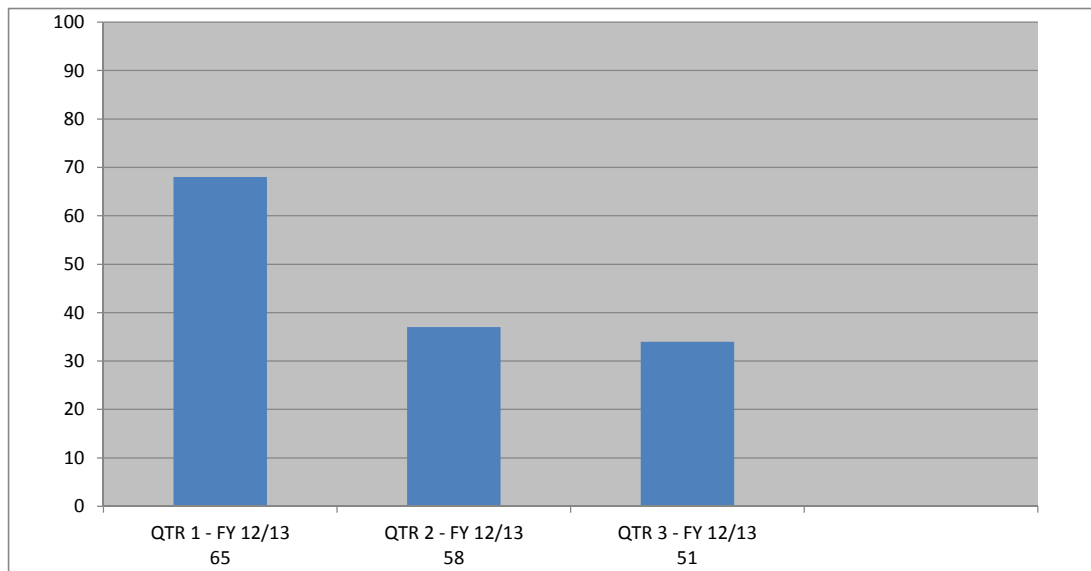
1O. Complete petitions to revoke probation within 30 days.
(Recorded as number of cases submitted)
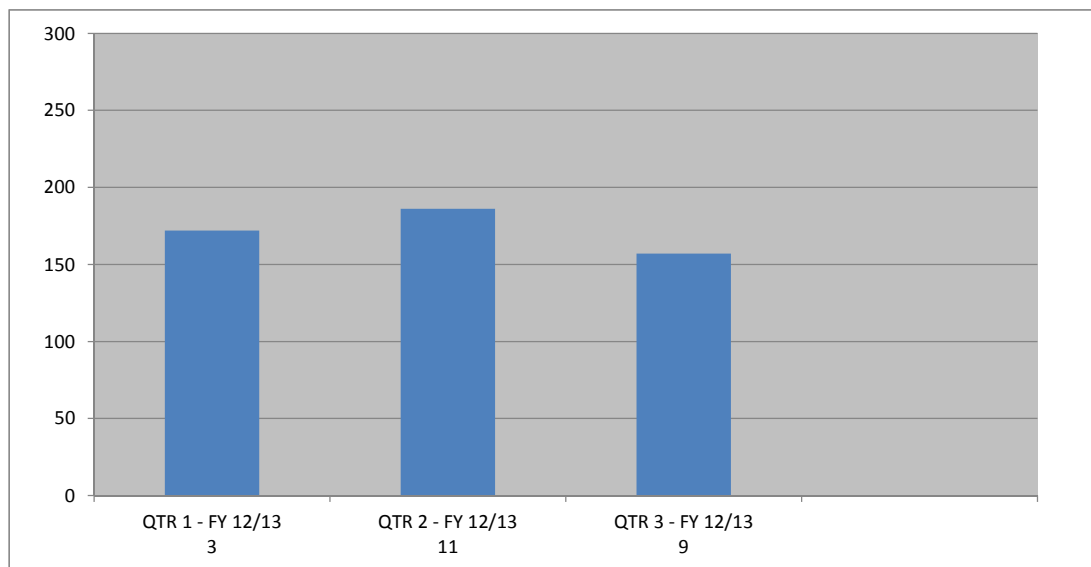
	QTR 1 - FY 12/13	QTR 2 - FY 12/13	QTR 3 - FY 12/13
	3	11	9

1P. Quarterly evaluate 5% of the Pharmacist Recovery Program (PRP) participants to ensure the PRP Contractor is in compliance with the contract.
(Recorded as number of participants in the PRP.)
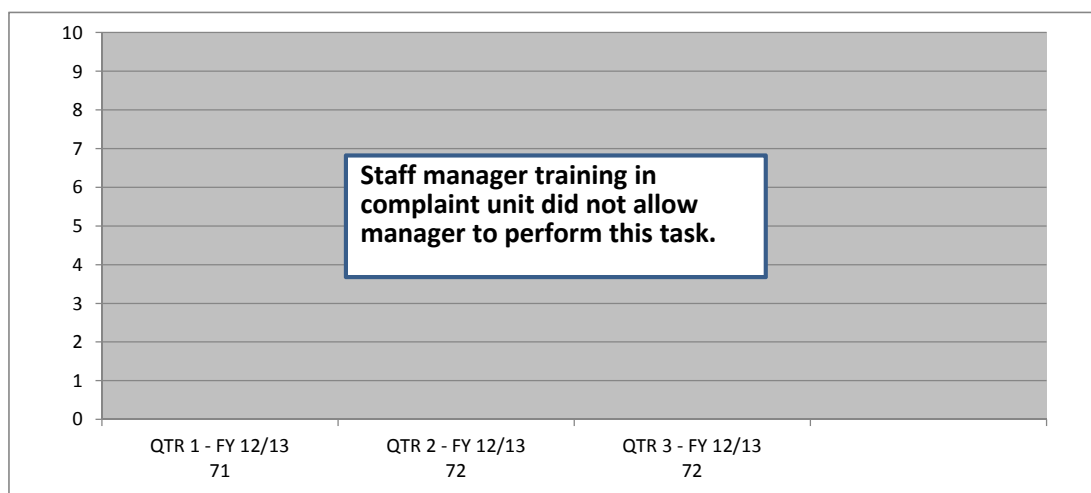
Staff manager training in complaint unit did not allow manager to perform this task.

	QTR 1 - FY 12/13	QTR 2 - FY 12/13	QTR 3 - FY 12/13
	71	72	72

1Q. Pursue disciplinary action, within 10 days, on a licensee closed a public risk from the Pharmacists Recovery Program.

(Recorded as number of participants closed a public risk)

	QTR 1 - FY 12/13	QTR 2 - FY 12/13	QTR 3 - FY 12/13
	1	0	2
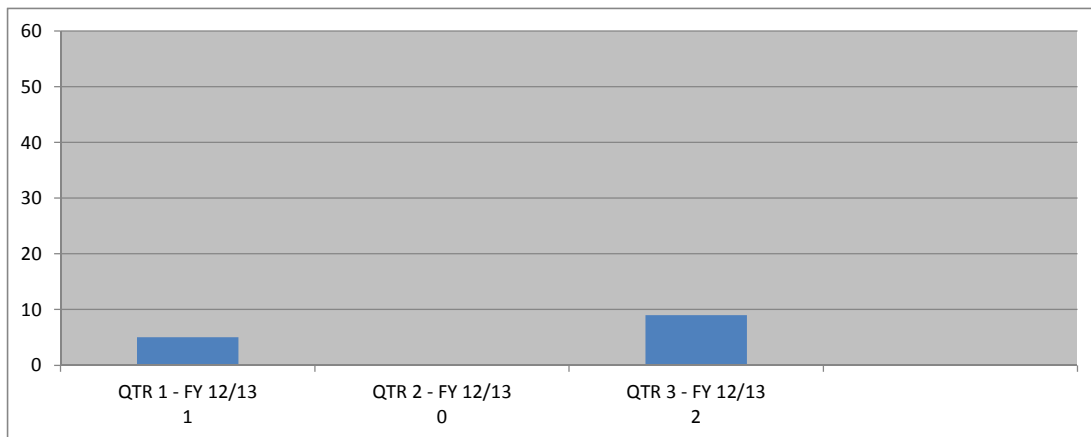
Attachment 11

California State Board of Pharmacy
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Phone: (916) 574-7900
Fax: (916) 574-8618
www.pharmacy.ca.gov

STATE AND CONSUMER SERVICES AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
GOVERNOR EDMUND G. BROWN JR.

STATE BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
ENFORCEMENT COMMITTEE PUBLIC MEETING
MINUTES

DATE: March 14, 2013

LOCATION: Sheraton Garden Grove
                        12221 Harbor Blvd.
                        Garden Grove, CA 92840

COMMITTEE MEMBERS
PRESENT:

                        Randy Kajioka, PharmD, Chair
                        Amy Gutierrez, PharmD
                        Rosalyn Hackworth, Public Member
                        Shirley Wheat, Public Member
                        Tappan Zee, Public Member

STAFF
PRESENT:

                        Virginia Herold, Executive Officer
                        Anne Sodergren, Assistant Executive Officer
                        Judi Nurse, Supervising Inspector
                        Kristy Shellans, DCA Senior Staff Counsel
                        Joshua Room, Supervising Deputy Attorney General

_____

The meeting was called to at 9:39. Chairman Kajioka welcomed everyone, a roll call was taken
and a quorum established.

I. Enforcement Committee Matters:

a.   **Request for Walgreens to Store Prescription Records Older than Five Years Outside a**
     Licensed Premises.

     California has requirements that all pharmacy records be readily retrievable in the licensed
     premises, and open to inspection by the board. These records are generally required to be
     retained for at least three years.

California law also permits the offsite storage of records if an offsite waiver has been approved by the board.

Al Carter, representing Walgreens provided the committee with information about the request. Mr. Carter provided an overview of the requirements for records retention to comply with CMS. Walgreens is requesting authority to store records off site after five years. The records storage is an issue because law specifies which persons have access to records, including pharmacy staff. The offsite storage vendor is not included in those authorized persons. Mr. Carter provided an overview of the proposed vendor, Iron Mountain.

Dr. Kajioka asked who would have access to the records offsite and was advised that records will be stored on a store by store basis and will only be accessed by Iron Mountain staff. Mr. Carter indicated that access to the records will be recorded.

Dr. Gutierrez ask for the timeframe Iron Mountain has to respond to a request for records and was advised that per the contract the records need to be provided within 48 hours.

Ms. Hackworth questioned the locations of the vendor and was advised that Iron Mountain have facilities throughout the state.

Ms. Herold provided an overview of the current records requirement and advised the committee that use of Iron Mountain is used as part of the offsite storage provisions. Ms. Herold indicated that the concern of the board may be the destruction of the records after the period. Mr. Carter advised Ms. Herold of the process for records destruction after the time period had elapsed. The contract specifies that the only authorized storage sites may be used and that if Walgreens fails to pay the vendor, the records would be returned to Walgreens.

Dr. Kajioka inquired is a single offsite storage waiver request could be used to facilitate approval and was advised that the request would need to be very specific. Mr. Carter indicated that Walgreens could provide a spreadsheet that includes each pharmacy and the location of the Iron Mountain facility where the records will be stored.

Motion: Approve Walgreens request.
M/S: Gutierrez/Hackworth

Public Comment
Dr. Gray advised the committee that no waiver should be required because records are only required to be maintained for three years.

SDAG Room advised the committee that while there is not requirement to obtain a waiver, Walgreens has requested one and as such should not be precluded for seeking and obtaining one.

Support: 3   Oppose: 0   Abstain: 0

b. **Request from Walgreens to Establish Pharmacy Kiosks in Workplace Clinics.**

Background

Several years ago, the board promulgated regulations (16 California Code of Regulation section 1713) to allow for the use of automated delivery devices, which are markedly like vending machines, to permit the furnishing of refill medication in specified circumstances. These circumstances include, that the patient must opt in to use the machine, the medication to be refilled through the machine is appropriate. The conditions are listed below in the highlighted segment of section 1713.

> 1713. Receipt and Delivery of Prescriptions and Prescription Medications Must be To or From Licensed Pharmacy
>
> (a) Except as otherwise provided in this Division, no licensee shall participate in any arrangement or agreement, whereby prescriptions, or prescription medications, may be left at, picked up from, accepted by, or delivered to any place not licensed as a retail pharmacy.
>
> (b) A licensee may pick up prescriptions at the office or home of the prescriber or pick up or deliver prescriptions or prescription medications at the office of or a residence designated by the patient or at the hospital, institution, medical office or clinic at which the patient receives health care services. In addition, the Board may, in its sole discretion, waive application of subdivision (a) for good cause shown.
>
> (c) A patient or the patient's agent may deposit a prescription in a secure container that is at the same address as the licensed pharmacy premises. The pharmacy shall

be responsible for the security and confidentiality of the prescriptions deposited in the container.

(d) A pharmacy may use an automated delivery device to deliver previously dispensed prescription medications provided:

(1) Each patient using the device has chosen to use the device and signed a written consent form demonstrating his or her informed consent to do so.

(2) A pharmacist has determined that each patient using the device meets inclusion criteria for use of the device established by the pharmacy prior to delivery of prescription medication to that patient.

(3) The device has a means to identify each patient and only release that patient's prescription medications.

(4) The pharmacy does not use the device to deliver previously dispensed prescription medications to any patient if a pharmacist determines that such patient requires counseling as set forth in section 1707.2(a)(2).

(5)   The pharmacy provides an immediate consultation with a pharmacist, either in-person or via telephone, upon the request of a patient.

(6) The device is located adjacent to the secure pharmacy area.

(7) The device is secure from access and removal by unauthorized individuals.

(8) The pharmacy is responsible for the prescription medications stored in the device.

(9)   Any incident involving the device where a complaint, delivery error, or omission has occurred shall be reviewed as part of the pharmacy's quality assurance program mandated by Business and Professions Code section 4125.

(10) The pharmacy maintains written policies and procedures pertaining to the device as   described in subdivision (e).

(e)   Any pharmacy making use of an automated delivery device as permitted by subdivision (d) shall maintain, and on an annual basis review, written policies and procedures providing for:

(1)   Maintaining the security of the automated delivery device and the dangerous drugs within the device.

(2) Determining and applying inclusion criteria regarding which medications are appropriate for placement in the device and for which patients, including when consultation is needed.

 (3) Ensuring that patients are aware that consultation with a pharmacist is available for any prescription medication, including for those delivered via the automated delivery device.

(4) Describing the assignment of responsibilities to, and training of, pharmacy personnel regarding the maintenance and filing procedures for the automated delivery device.

(5) Orienting participating patients on use of the automated delivery device, notifying patients when expected prescription medications are not available in the device, and ensuring that patient use of the device does not interfere with delivery of prescription medications.

(6) Ensuring the delivery of medications to patients in the event the device is disabled or malfunctions.

(f) Written policies and procedures shall be maintained at least three years beyond the last use of an automated delivery device.

(g) For the purposes of this section only, "previously-dispensed prescription medications" are those prescription medications that do not trigger a non-discretionary duty to consult under section 1707.2(b)(1), because they have been previously dispensed to the patient by the pharmacy in the same dosage form, strength, and with the same written directions.

In 2009-10, Pharmacist Consultant Philip Burgess, on behalf of a manufacturer of one of these machines (Asteres), sought an exemption to permit the use of these machines in areas away from adjacent to the licensed pharmacy premises. The board did not approve the request, and requested more information about how and where the kiosks would be used. One concern was that the board considered that it lacked the ability to provide the exemption sought (which would have required a regulation change). There was no further interest pursued by Asteres after the January 2010 meeting. Materials covering some of these discussions were provided in the materials for the meeting.

Presentation and Discussion:

Mr. Carter, representing Walgreens, discussed a request that would allow for Walgreens to place kiosks in workplace clinics. Mr. Carter advised the committee that the workplace

clinic is on an employee campus serves a large volume of employees. Mr. Carter discussed the Walgreen's capability to provide pharmacy services via a kiosk. Mr. Carter provided an overview of the types of services that are provided at the clinic and how Walgreens would provide medication. Mr. Carter highlighted that the kiosk would not be stored in the clinic, but would be housed across the street in a separate building. The kiosk would be in a secured building and advised the committee that a patient would have access to a pharmacist via a video link 24 hours a day.

Mr. Carter provided a PowerPoint presentation that walked the committee through the process from enrollment to prescription dispensing. Mr. Carter discussed who will put the medications in the machine and the safety features of the machine including barcoding. Safety features include a log-in and pin or a fingerprint scan and pin number. A camera is also used to take pictures for auditing purposes. Mr. Carter discussed the specifics of the enrollment process. Mr. Carter indicated that no refrigerated items or bulk items would be provided via this kiosk. [A copy of the PowerPoint presentation is provided at the conclusion of the meeting minutes.]

Dr. Kajioka asked if an authorized agent could pick up the prescription and was advised that there is a consent process in place to allow for this. The authorized agent is limited to just family members. Dr. Kajioka asked what process would occur if a pharmacist determined that consultation was required and was advised that the patient would be required to go to the pharmacy to obtain the medicine.

Mr. Room discussed some possible options the board could consider depending on the full nature of the request. Ms. Shellans indicated that her legal opinion is more limited and that current law only allows for refill prescriptions. Ms. Shellans indicated that expansion to allow for new prescriptions would require a regulatory change.

Ms. Hackworth asked what others services or items are in the room that will house the kiosk and was advised that Walgreens believes the kiosk will be the only item in the room. Ms. Hackworth also asked what payment mechanisms are accepted.

Dr. Gutierrez asked if schedule II controlled substances would be dispensed via the kiosk and was advised that Walgreens would want to include such medications if allowed by the board.

Dr. Nurse asked who would be filling the kiosk and was advised that it will be filled by pharmacists. Dr. Nurse was also advised that the prescriptions will be filled at the local Walgreens and delivered to the Kiosk, not filled by a central fill pharmacy.

Ms. Herold expressed concern about allowing a kiosk not adjacent to the facility because the board would lose control of where drugs are stored and dispensed from.

Mr. Room clarified that under the current regulation the board lacks the authority to waive the requirement that the kiosk be adjacent to a pharmacy. Further, Mr. Room noted, in response to a comment by Dr. Nurse about access by board staff for investigative purposes, that the proposed construct could be problematic.

Dr. Kajioka indicated that he believed there was not sufficient information to act at this time.

Motion: Deny request but have the board re-evaluate the regulation and determine if changes are necessary to address emerging technologies.

M/S: Gutierrez/Hackworth

Committee Member Zee suggested that perhaps Walgreens could work with counsel to develop language that could address the boards concerns as an interim solution to allow for a temporary waiver to be considered at a future committee meeting. Mr. Carter expressed a willingness to work with the board.

Mr. Carter indicated that they are aware of a few other states that allow for the use of a Kiosk as being proposed and offered to survey and provide information to the board.

Support: 5   Oppose: 0   Abstain: 0

c. **Request from Kaiser for a Temporary Waiver of Secure Prescription Blank Prescribing Requirements for Controlled in a Closed Health Care System.**

Background

Existing law requires the use of security prescription forms for written prescriptions for controlled substances.   Security prescription forms must be printed by state-registered printers and conform to specific requirements to make forgery of these forms difficult. There are few exceptions to the use of these specialized forms when a prescriber writes a prescription.

Schedule III-V drugs may be prescribed orally; only in very limited cases, may Schedule II drugs may be orally prescribed.

In 2010, the DEA released Interim Final Rules to permit the e-prescribing of controlled substances, and all e-prescriptions for controlled substances must the DEA's regulatory

requirements, including a third-party audit of the computer application certifying that I meets the requirements of the DEA regulations.

E-prescribing is not faxing (where a prescription is actually written and signed by the prescriber, and a facsimile is transmitted to the pharmacy). Faxing is not allowed for controlled substances, although faxed prescriptions for Schedule III- V prescriptions are sometimes treated as oral prescriptions by pharmacies which if received, must verify the fax with the prescriber's office. (Note, a security prescription form, if faxed, is required to display a "VOID" impression on the faxed document, showing that the fax is not a legitimate written prescription.)

Presentation and Discussion:

Dr. Steve Gray, representing Kaiser Permanente, provided a brief overview of Kaiser Permanente including its closed integrated system. Dr. Gray provided a brief overview of the concerns with their current process and handling of schedule III and V controlled substance prescriptions. Dr. Gray indicated that the result of their current process is delays in delivering the pharmacist services, the quality of care as well as security issues. Dr. Gray indicated that the proposal would reduce drug diversion as well as diversion of security of prescription forms. Dr. Gray indicated that this temporary solution will also provide for better quality of care for patients. Dr. Gray advised the committee that the proposal was discussed with representatives of the Department of Justice. Dr. Gray indicated that the DOJ recommended that this issue be discussed by the board prior to implementation.

David Kavanse, national leader and Vice President for Pharmacy Services within Kaiser, provided a powerpoint to discuss the overview of the current manual system as well as the proposal alternative process. Mr. Kavanse advised the board that they were hoping to receive guidance and feedback on the proposal. Mr. Kavanse discussed the current process for electronic prescriptions, not including controlled substances. Mr. Kavance indicated that controlled substances cannot follow the same process because of DEA rules and provided an overview of the current workflow process. Mr. Kavance indicated that the current process is extremely inefficient and briefly highlighted several options to remedy this and the basis for ruling out these other alternatives.

Mr. Kavance provided specific details for the interim solution that includes a prescriber using plain paper to prescribe the controlled III-V substance. This prescription would have a "wet" signature and date of the prescriber. This prescription would be provided to the patient who is then responsible for taking the prescription to the pharmacy. When presented to the pharmacy, the prescription would be confirmed with the electronic medical record for confirmation. If confirmed through this process, the prescription would be treated as a valid and legitimate order and the medication would be dispensed. If confirmation was not received, the pharmacy would contact the prescriber to confirm the legitimacy of the prescription prior to dispensing or the pharmacy would refuse to dispense the medicine.

Mr. Kavance indicated that the DOJ has indicated that if the board is agreeable to the proposed interim solution, the DOJ would also be agreeable to approve this process. Mr. Kavance stated that he believe Kaiser can fulfill the intent of the security paper provisions through this interim process because it is a closed healthcare system. [A copy of the powerpoint presentation is provided following these minutes.]

Dr. Kajioka asked several questions about this proposal. Dr. Kajioka asked about what notations would be made in the electronic medical record if a prescriber is contacted to confirm the legitimacy of a prescription and was advised that Kaiser would confirm how and if such information would be notated. In response to Dr. Kajioka's question about an official response from the DOJ on this proposed solution, he was advised that although DOJ cannot provide an official response on this proposal, DOJ staff did indicate that the proposal appeared to comply with the intent of the law. Dr. Gray also spoke about the security features of the Kaiser System and controls of which staff can order a prescription. Dr. Gray indicated that it this system would address the issue of someone calling in a fake oral prescription and well as the diversion of security prescription blanks.

Ms. Herold asked if oral prescriptions for schedule III-V prescriptions would still be allowed in the Kaiser system along with this proposal and was advised that Kaiser would be unable to totally eliminate oral prescriptions.

Mr. Room asked how from the prescriber's perspective how they are meeting the requirements of the Health and Safety Code as the proposed solution violates the health and safety code provisions. In response Mr. Room was advised that the question has not been considered or asked before.

When asked about the desired outcome of the presentation, the committee was advised that Kaiser was directed by the DOJ to discuss their proposal with the board to ascertain any concerns the board may have as well as guidance of the board to determine if the proposal could be implemented from the pharmacy standpoint. This information would then be brought back to the DOJ who establishes the requirement for the security prescription requirement.

A motion was made to recommend on behalf of the Enforcement Committee that in a closed loop system with electronic validation as set forth in the presentation that the Board of Pharmacy's Enforcement Committee has not objection to it provided that Kaiser works with the DOJ in terms of their administration and enforcement of the particular health and safety code. (This motion did not receive a second and was later amended.)

Dr. Kajioka indicated that two issues need to be addressed, that of the prescriber not using security paper to write a prescription as required by the health and safety code as well as the a pharmacy filling such a prescription. Dr. Kajioka indicated that the board would require documentation by the DOJ of its confirmation to waive the health and safety code provisions to address both issues.

Dr. Gray advised Dr. Kajioka that the DOJ does not have a problem with a prescriber using plain paper to prescribe schedule III-V prescriptions.

SDAG Room reiterated that he is unaware of any authorization for a prescriber to issue a prescription for a schedule III-V controlled substance other than on a secured prescription form.

Mr. Kavance acknowledged the concerns raised by the committee and indicated that the concerns would be brought to the DOJ and urged the committee members to take action on the earlier motion.

In response to a question by Dr. Gutierrez about other states that are allowing this process, she was advised that CA if the first state that has been approached in part because Kaiser does not have the same health and safety code requirements in other states. Dr. Gutierrez also sought input from enforcement staff and indicated that a person wanting to defraud the system would be able to do so. Dr. Nurse responded that one of the inherent safe guards of a security prescription is that is cannot be reproduced readily. Dr. Nurse highlighted potential ways to defraud the proposed solution.

Ms. Herold indicated that she firmly believes that the board lacks the authority to act on this proposal. Ms. Herold indicated that DOJ also lacks the authority to accept this waiver as well. Ms. Herold reminded the committee that unless the law authorizes something, it cannot be done. Ms. Herold indicated that she would strongly advise the board to not consider this waiver until the statute is amended. Ms. Herold discussed some of the challenges with the current motion including the fact that it could apply to any HMO. Ms. Herold reminded the committee that the board is awash in drug diversion cases and indicated that this proposal is very dangerous.

Dr. Gray advised the committee that the DOJ has indicated that they do not believe that the Health and Safety Code does not prohibit this and that the DOJ could exercise some enforcement discretion.

SDAG Room indicated that he does not believe this proposal is allowed under current law and indicated that he would need to discuss this proposal with colleagues the DOJ to determine if the law is in fact flexible enough to allow the proposal without a statutory change. Mr. Room advised the committee that he can convene a meeting within the DOJ to ensure everyone within the DOJ is in agreement on this issue.

Tappan suggested that there are two issues. This is a regulatory enforcement issue that is under the purview of the DOJ. Mr. Zee indicated that it appears that the DOJ is hesitant to take action without some input from the Board of Pharmacy.

Motion: Move that the board recommend to the DOJ that the board does not have an objection to the plan as set forth by Kaiser a closed system to use plain paper with the caveat that Kaiser counsel meet with DOJ to discuss the enforcement issues.

M/S: Zee/Wheat

Mr. Room clarified that this would serve as a policy statement that would be made consistent with the law.

Ms. Hackworth indicated that she does not believe that a motion is necessary given that the DOJ could always have internal discussions.

Support: 3   Oppose: 2   Abstain: 0

d. **Board Comments Submitted in Response to the Federal Department of Justice, Drug Enforcement Administration's Notice of Proposed Rulemaking Related to Disposal of Controlled Substances [Docket No. DEA-316]**

Background

In 2009, California adopted guidelines for the take back and destruction of unwanted pharmaceuticals from the public so they could be appropriately destroyed and not misused by others or flushed down the drain. However, the guidelines were only guidelines until the FDA promulgated regulations to deal with the collection and destruction of controlled substances.

The DEA developed proposed regulations to deal with the take back and destruction of controlled substances and released them for comment in December 2012, with a final comment date of February 19, 2013. At the February Board Meeting, the board directed that comments be submitted to conform to board policy and California's guidelines in this area.

Discussion:

Dr. Kajioka provided an overview of this issue and discussed the information about drug take back and the comments submitted in response to the DEA's request for comments on the proposed rule change. Dr. Kajioka reviewed the preferred method the board is advocating for drug take back to reduce the diversion of such items.

There was no committee or public comment.

e. **Proposed Statutory Provisions to Prevent a Wholesaler from Purchasing Prescription Medication from a Pharmacy When the Pharmacy Did not Purchase the Medication from the Wholesaler**

Prior to discussion on this issue Mr. Room provided a cautionary note about the topic to be discussed. Mr. Room advised the committee that the discussion needs to remain very general in nature and should not include the names of any businesses, etc.

Discussion:

Ms. Herold provided an overview of the issue and referenced materials in the committee materials. Ms. Herold indicated that under investigation is a wholesaler that is purchasing drugs from nonresident pharmacies, drugs that are short supply. Ms. Herold referenced a congressional report that was provided in meeting materials on this issue.

Ms. Herold provided an explanation for the legislative proposal that would prohibit a CA licensed wholesaler from purchasing drugs from a nonresident pharmacy. Such a prohibition currently exists for CA pharmacies however the law does not appear to explicitly prohibit such a transaction when the pharmacy involved in the transaction is not located within CA.

Ms. Herold reviewed the legislative proposal. [A copy of the language is provided as an attachment to the meeting summary.]

Mr. Room discussed the intent of the legislative proposal and outlined the current law relating to this area. The prohibition currently only applies to CA pharmacies however there is no similar provision for nonresident pharmacies.

Ms. Shellans advised the committee that there are other provisions in pharmacy law that may also need to be changed if the board is interested in doing policy changes in this area.

MOTION: To make a recommendation to forward the legislative framework to the full board for consideration along with any other statutory amendments that may be necessary to accomplish the goal.

M/S: Hackworth/Kajioka

Note: The committee did not vote on the prior motion and no action was taken on this item.

<u>Public Comment</u>

Dr. Gray suggested that the topic warrants more discussion and sought clarification on the intent.

Mr. Room indicated that under current law, a pharmacy is allowed to sell a drug that is currently in stock to a wholesaler to alleviate a shortage, however the law does not allow a pharmacy can purchase drugs in short supply and then resale it.

Mr. Room indicated that three conditions must be met to allow for a sale from a pharmacy to a wholesaler from other than that from which they originally purchased the drugs.

1. The pharmacy already has it in stock

2. The drug is a shortage and

3. A person will be denied health care

Dr. Nurse discussed some of the history of the current law and the problems that the board is currently encountering. Further Mr. Room clarified that the board has the authority to

Gil Carpenter expressed concern over the legislative proposal that would limit the ability for pharmacies and wholesalers to conduct business relationships that ensure patients receive their medications when a shortage occurs. Mr. Carpenter discussed the type of business he currently operates that allows him to fill a given order for a drug in short supply through a network of wholesalers and serves as a clearinghouse to ensure patients receive the medications they need.

The committee discussed the issue and the issues surrounding the practices of primary and secondary wholesalers.

Dr. Kajioka indicated that this discussion may be premature until the board has the opportunity to understand more about the case currently pending.

Tony Park, CPhA indicated that several pharmacies are confused about what the preconditions are for transactions to occur. He recommended that the board should provide clarity on these issues.

The committee did not vote on the prior motion and no action was taken on this item. The item will be discussed by the committee after further information is provided.

II. Discussion on the Implementation of California's Electronic Pedigree Requirements for Prescription Medication

a. **Update on the Status of Proposed Regulations to Implement Serialized Numeric Identifiers, Grandfathering and Manufacturer Reporting of How the 50 Percent Threshold of Serialized Products on January 1, 2015. (Proposal to Add Title 16, California Code of Regulations Section 1747 and 1747.1)**

Discussion:

Ms. Herold provided an update on the regulation package undergoing promulgation relating to the SNI requirements as well as the grandfathering provisions. There were no committee or public comments on this item.

b. **Presentation and Questions from the Pharmaceutical Supply Chain on Their Readiness to Meet California's Staggered E-Pedigree Implementation Schedule**

Presentation by Bob Celeste

The committee heard a presentation from Mr. Bob Celeste representing GS1. Mr. Celeste provided information the GS1 Track and Trace document. Mr. Celeste indicated that the document is a preliminary document at this point. The document is being used by some companies to move forward with pilots, but may change as a result of pilot projects as well as further review of the overall process. [A copy of the presentation as well as the referenced GS1 Track and Trace and document is attached to these minutes.]

Mr. Celeste provided an overview of the document as well as how to use the materials. Mr. Celeste noted that as companies gain experience with pilots it is assumed that the document will change dramatically. The standards are designed with three primary functions: identify necessary elements, capture data and sharing data with trading partners and the document is formatted following those three functions.

At the conclusion of his presentation Mr. Celeste advised those in attendance that GS1 is working with manufacturers to ensure that they have a properly encoded and well defined barcode.   GSI is also offering workshops to take people through the document, dedicating a day to going through the details. These workshops also provide a forum for individuals to discuss their particular implementations and any questions they may have.

Mr. Room questioned Mr. Celeste about the use of the EPCIS standard to develop another fashion to comply with the board's law noting that is appears to be possible to build such a standard. Mr. Celeste indicated that there is a general belief that at minimum the standard

could meet the intent of the e-pedigree requirements using the EPCIS model. Mr. Celeste noted that the EPCIS model is more flexible. Mr. Celeste indicated that there are some issues surrounding the architecture of the system. Mr. Celeste discussed some of the rules in place for a distributed model and some of the challenges using of the centralized model because of the issues of data governance and who will have access to view and see information. Mr. Celeste discussed one of the general concepts of the guidance document is of the movement of product through the supply chain involved two trading partners both reporting the transaction.

There was no additional committee or public comment.

Presentation by Liz Gallenagh & John Howells (HDMA) Drop Shipment PPT

The committee heard a presentation from Liz Gallenagh and John Howells representing HDMA.   The presentation focused on the use of drop shipments by members of the supply chain. [A copy of the presentation is attached to these minutes.]

Dr. Room asked at what point the distributor is advised of the transaction and was advised that it varies and was provided with several difference scenarios.

Ms. Herold asked about how brokering by a wholesaler would fall into this model and was advised that the information being provided does not include brokering, rather is limited to just drop shipment information.

The committee discussed some of the parameters of brokering and how it may work as well as if the possibility exists for a broker to leverage the drop shipment model to compromise the pedigree process.   The committee was advised of some of the changes between the brokering model versus the drop ship model.

Mr. Room pointed out that the manufacturer designee drop ship model described would not realized the benefits of a regulation in this area because it does not comply with section 4163.1.

Mr. Room discussed possible regulatory language on inference, certification and expectations on how to access data for purposes of inspections. (Draft language was made available and those in attendance were advised that the language was also posted on the board's web site.

Mr. Room provided an overview of the concept of certification and what is required.

Public Comment on draft regulation:

HDMA sought clarification on some of the terms used in the language.

Dr. Gray provided some other information for consideration (need to take from webcast) SDAG indicated that there does not appear to be robust security features on the shipment of cases and pallets and as such the language is narrowly drafted.

Representatives from Walgreens provided information on the case size. They indicated that the number of units varies based on the size of the units and can range from 39 to 144. Walgreens offered to provide the board with information on the number of units in a case. Walgreens spoke in need of inference in their distribution center. When asked what percentage of cases go through their distribution center without being broken down, Walgreens indicated that an unsealed case going through to their pharmacies would be an exception.

SDAG asked for the percentage of cases that will move through the system without being opened. This information is necessary to assess the risk of allowing items to move using inference.

Public comment from another individual indicated that it may be a challenge to define a case because it is continually changing. Perhaps the solution would be to rely on the case security such as tamper evidence tape etc. The individual indicated that provided extra seals would not provide any greater level of security and also expressed concern about treating different cases differently.

Ms. Herold underscored the need for the board to have comments on the draft language to ensure that the regulation is appropriate, ensures the necessary protections are in place but does not prevent the flow of drugs through the supply chain.

Dr. Gutierrez indicated that a case should really be something some can pick up and suggested perhaps rather than specifying a number of units contained in the cases as a definition to rather a weight limit.

c. **Discussion on the Use of Drop Shipments in an E-Pedigree System**

Discussion:

The committee was advised that board staff released a solicitation request through the board's email notification system that the board was seeking information on drop shipments from members of the supply.

The committee heard comments from John Valencia, representing a number of clients. Mr. Valencia indicated that a number of the clients he represents need guidance for drop shipments. Mr. Valencia spoke about a drop ship model that is used for some specialty

products. He referenced comments submitted and detailed some changes between the HDMA model discussed earlier in the meeting and the proposed solution being offered by his clients. Mr. Valencia urged the committee to discuss the issue and move forward the language for discussion as it will solve a real dilemma for a small but specialized area.

Mr. Room clarified that the proposal appears to specify that there would be a direct connection between the manufacturer and the physician's office or clinic. Mr. Room noted that the proposed solution would work for their business model, but not for all.

Mr. Valencia indicated that his clients need to be in some place of certainty to ensure businesses know how to move forward as the implementation date moves closer. Mr. Valencia reminded the committee that the billing relationship is not what is important in tracking a pedigree.

Mr. Room indicated that he did not have any concerns from a legal perspective with the draft language.

Ms. Herold again requested information from industry to ensure that the board has the necessary information to ensure the development of the language is appropriate.

Committee Member Wheat requested information about the possibility of splitting the committee and was advised that this should be discussed by the board. Ms. Wheat indicated that it is very hard to make decisions on information that is provided to the committee members during the meeting.

Dr. Gutierrez asked if it was possible to maintain the committee meeting so it would be back to back meetings.

III. **Public Comment on Items Not on the Agenda/Agenda Items for Future Meetings.**

Discussion

Dr. Kajioka requested comments for public comment for items not on the agenda.

Jonathon Nelson, CSHP addressed the committee to discuss drug shortages and requested that this topic be discussed by the board at a future board meeting.

Douglas Barcon, representing CSHP and as an individual, addressed the committee to discuss the issue of drug returns from skilled nursing facilities. Pharmacist Barcon indicated that USP Section 1196 prohibits the de-blistering of a returned medication to be reused. He expressed concerned about the process to handle a drug returned from the skilled nursing

facility to a drug repository and encouraged the board to look at the issue of drug repositories and how to manage this.

Dr. Kajioka adjourned the meeting at 2:11 p.m.

Introduction to *ScriptCenter*®
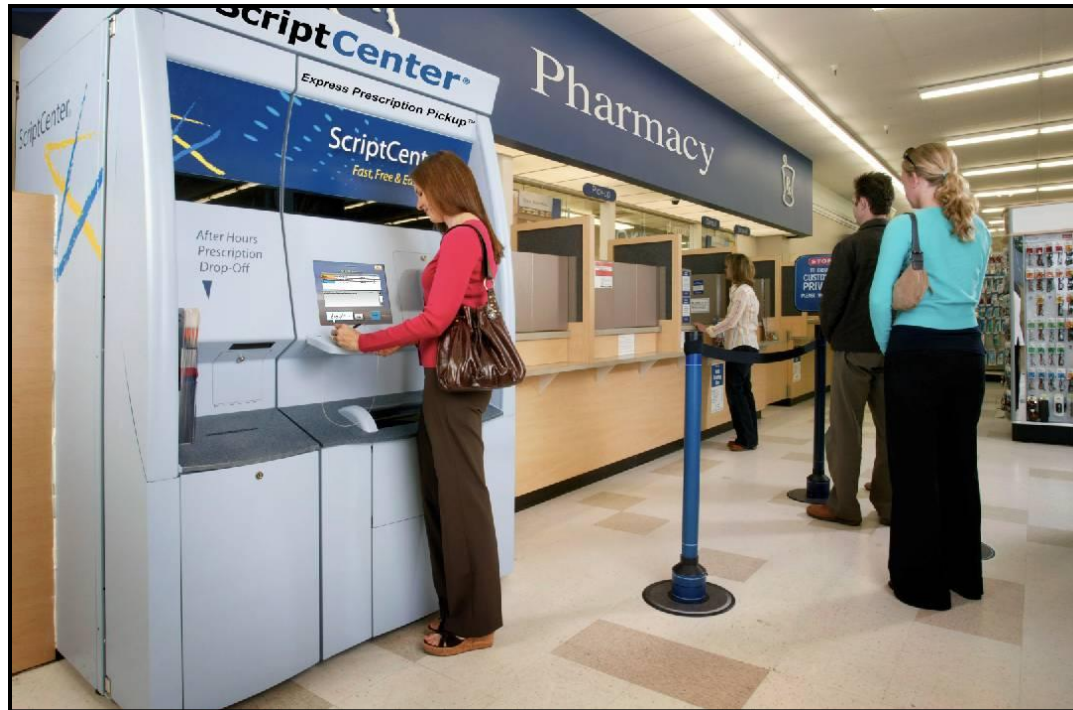
ScriptCenter Self-Checkout

- Pharmacy staff loads finished prescriptions into ScriptCenter.

- Customers pick up and pay for prescriptions using ScriptCenter.

- Customers can pick up after hours.*

*Requires State Board of Pharmacy approval

DELIVERED BY
ASTERES®

ScriptCenter in the Pharmacy

Fill → Load → Pay

- Customer orders prescription as usual
- Pharmacy fills prescriptions as usual
- Prescription put in ScriptCenter bag, scanned & loaded anywhere, single or batch

- Customers purchase from ScriptCenter

DELIVERED BY
ASTERES®

How customers use *ScriptCenter*

- One-time Enrollment
- Log In
  - Login ID & PIN
  - Fingerprint scan & PIN
- View prescriptions list
- Sign and acknowledge
- Pay
- Remove from bin
- Take receipt

DELIVERED BY
ASTERES®

Positive ID

- Log In
  - Login ID & PIN
  - Fingerprint Scan & PIN
- All customers sign for prescriptions
- Signature Report printed in pharmacy
- Photo taken with signature
- Fingerprint for staff identification

Safety and Security Features

- One prescription per bag
- Bar code assures patient/Rx match
- Biometric tracking of all bag/trays that are handled by staff
- Electronic signature and photo log
- Equipped with floor bolts and door locks
- Privacy screen for confidentiality

000044196
Barcode Rx Tracking

Biometric Staff Login & Tracking

Consumer Photo Capture
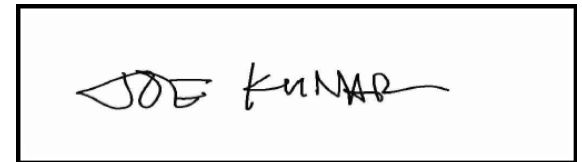
JOE KUMAR
Consumer Signature Capture

DELIVERED BY
ASTERES®

ScriptCenter Benefits

- ## Customer Benefit:
  - No waiting in line at counter
  - Pickup when pharmacy is closed*
  - Takes less than a minute

- ## Pharmacy Benefit
  - Attracts & retains Rx customers
  - More pickups without more staff*
  - Extends pharmacy hours without additional staff*

*Requires State Board of Pharmacy approval

DELIVERED BY
ASTERES®

ScriptCenter®

Enrollment Process

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ScriptCenter are trademarks of Asteres Inc.

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The information within this document is proprietary and confidential. Asteres and ScriptCenter are trademarks of Asteres Inc.

ScriptCenter can generate cross-selling and other promotional opportunities through use of the configurable customer receipt given at the completion of the enrollment process

ScriptCenter®

Express Prescription

Delivery

ScriptCenter

Log In

Enroll

3. Order your refill as usual and pick it up ... Anytime!

Single Prescription Access

Español

ScriptCenter

Scan Your Fingerprint or Enter Your User ID

User ID: Enter User ID

Next >

Forgot ID?

| 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | Backspace |

| Q | W | E | R | T | Y | U | I | O | P |

| A | S | D | F | G | H | J | K | L | Enter |

| Z | X | C | V | B | N | M |

ScriptCenter

Enter Your PIN

User ID: **marlene**

PIN: ****

Next >

Forgot PIN?

1	2	3	Backspace
4	5	6	Enter
7	8	9	
0			

Quit
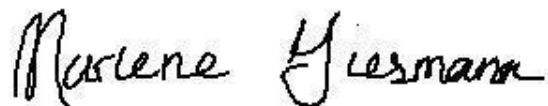
ScriptCenter

Read and Acknowledge

Name	Item	Rx #	Child Safety Cap
MARLENE GIESMANN	PRAVACHOL 40MG TABLET #30	2500600-001	Yes

- I am picking up these prescriptions.

- The person for whom the prescription was written is eligible for prescription benefits.

- The patient authorizes the release of all information recorded in this transaction, the prescription to which it corresponds, and the subsequent claims to the insurance carrier, policy holder, plan sponsor, and/or employer.

- He or she assigns payment for this transaction directly to the pharmacy.

Marlene Giesmann

Clear

Accept >

24

ScriptCenter can generate cross-selling and other promotional opportunities through use of the configurable customer receipt given at the completion of the delivery process

One Touch Family Pickup

Pickup and pay for your family's prescriptions in one easy transaction

- Adding family members to your account is easy
  - ID & PIN for adults
  - Rx & birth date for children
- Once added, everyone's prescriptions will show up in your cart

ScriptCenter®

Pharmacy Workflow

ScriptCenter
Pharmacy Workflow

Pick-up

Customer

Request refill

Label prints
with Indicator

Prescription is
loaded into
ScriptCenter

Prescription is
linked to
ScriptCenter bag

Prescription
is filled

Place monograph and prescription in ScriptCenter bag

- Retrieve monograph and prescription from pharmacist after quality assurance check has been completed
- Ensure the monograph and prescription match
- Place monograph and prescription into an appropriate size ScriptCenter bag
  - Ensure you can scan the prescription # thru the bag
- Seal the ScriptCenter bag and remove the tab completely
- Place sealed bag at the ScriptLink station

Scan prescription number

- Using the barcode scanner at your workstation scan the prescription number on the monograph thru the ScriptCenter bag
  - Make sure to scan the prescription number barcode, as there are multiple bar codes on the monograph
  - If the wrong barcode is scanned AsteresCentral will give you an error of "RX was not found"
- The prescription will appear on the screen in the prescription data area of the ScriptLink tab along with other relevant prescription information
- Verify that the information is correct and click "Next"
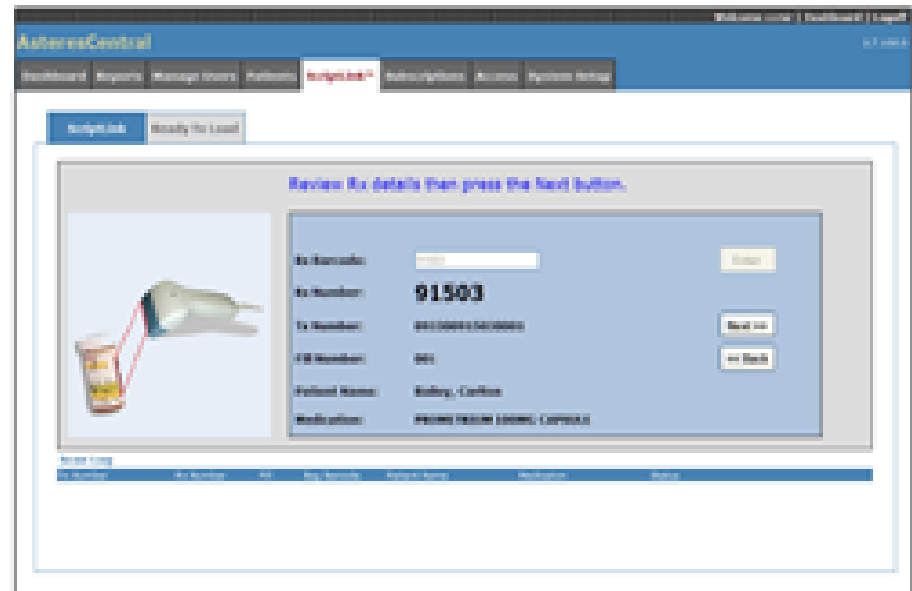
Scan the ScriptCenter bag

- Scan the ScriptCenter bag barcode located on the plastic header of the ScriptCenter bag

- The ScriptCenter bag barcode number will appear in the Asteres Bag Barcode section of the ScriptLink tab

- Double check that the bag barcode number entered on the screen matches the ScriptCenter bag you are holding and click "Next"
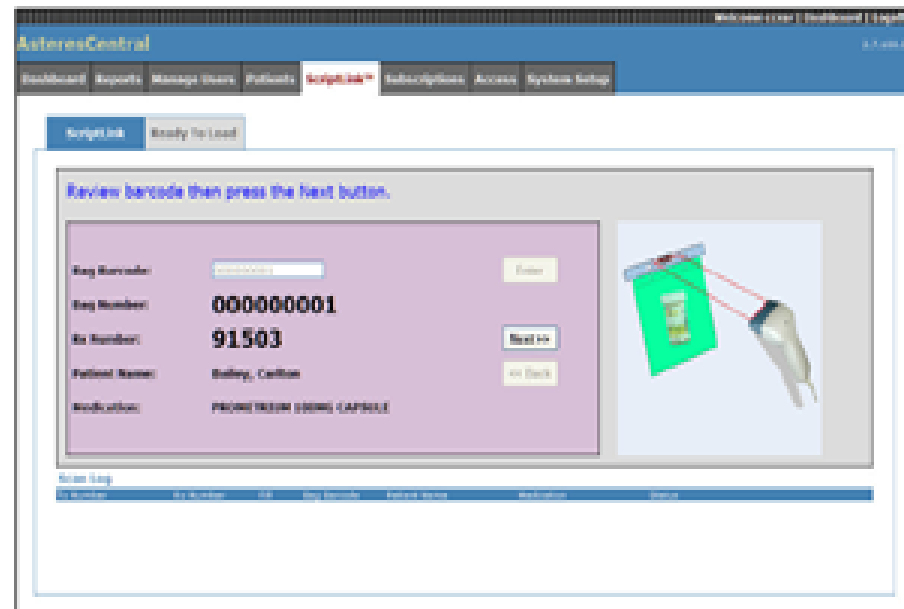
Step 4 : Final verification

- To finish linking the prescription to the ScriptCenter bag, verify that the Rx number and bag number on the screen match what you are holding and click "Finish"
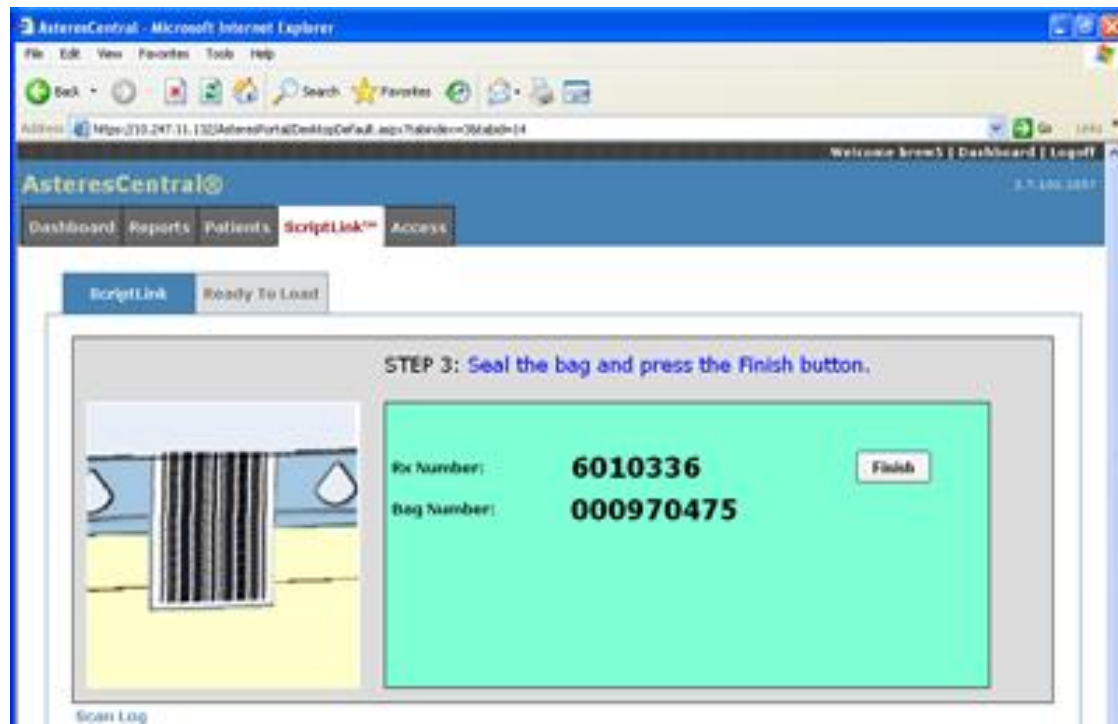
Load linked bag into ScriptCenter

- The package is now ready to be loaded into the ScriptCenter tray
- The packages can be loaded in any position, in any tray, on any platform
- Push the tray all the way back into the ScriptCenter platform
- If the bag was not linked ScriptCenter will place it in the unload tray and label it as an unknown package
- Make sure to check the unload tray for expired, problem, or unknown packages
- After the door to ScriptCenter is closed, an inventory will be generated to determine what packages have been loaded or removed

Access & Security

- Easy loading with front or rear access

- Quick login with biometric ID

- Security checks using barcode technology

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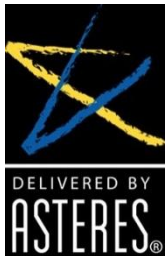
Interim Workflow for Controlled Substance Prescriptions (CIII-V) at Kaiser Permanente

March 2013

Agenda

- **Current Situation**

- **Long Term Solution**

- **Interim Workflow Options Considered**

- **Recommended Interim Workflow**

- **Benefits Summary**

Controlled Substance Prescriptions (CIII-V) at Kaiser Permanente

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- **Current Situation**

  - Not ePrescribing for controlled substances

  - Standard procedure is to fax CIII-V prescriptions from KP medical offices to KP pharmacies

    - Printed from KP EMR system on plain paper

- **Long Term Solution**

  - ePrescribing once DEA requirements are met, including certification for KP HealthConnect (KPHC) and ePIMS

    - A limited pilot is scheduled in Q3/Q4 2013 for SCAL to follow certification

    - Uncertainty relative to pilot success and therefore overall ePrescribing program deployment schedule

  > ## We believe an interim solution is needed

■ Current Workflow – Faxed Copy
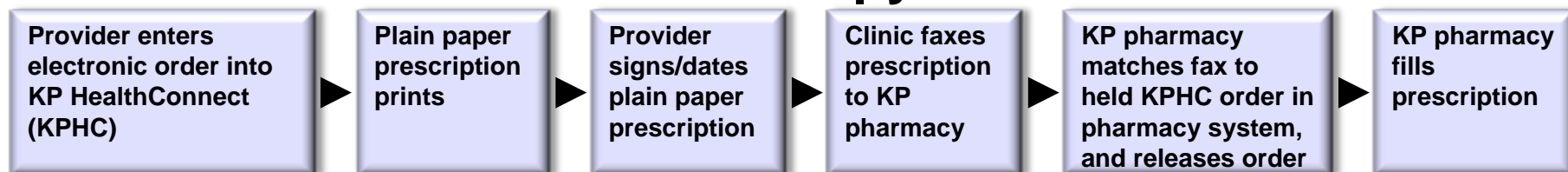
Provider enters electronic order into KP HealthConnect (KPHC)	▶	Plain paper prescription prints	▶	Provider signs/dates plain paper prescription	▶	Clinic faxes prescription to KP pharmacy	▶	KP pharmacy matches fax to held KPHC order in pharmacy system, and releases order	▶	KP pharmacy fills prescription

Advantages	Disadvantages

Are we Compliant?
•Compliant with current federal and state requirements
 	
Is it Accurate?
•Plain paper prescription matches KPHC electronic order
•Assures medical and prescription record is complete in KPHC
 	
Is it Timely/Efficient?
•No, multiple additional steps and issues for medical office and pharmacy
	Additional Steps
	•Prescriber must sign hard copy
	•Office personnel must scan/fax
	•Office personnel must shred original signed prescription
	•Pharmacy must receive fax, print KPHC order and match to fax
	•Patient must wait for fax to arrive in pharmacy
	
	Issues
	•Pharmacy call backs to the MD/Clinic office
	   • Patient arrives prior to fax (reduces member/staff efficiency)
	   • Delay in sending fax (batch processing)
	   • Problems with fax network/transmission
	   • Fax sent to wrong pharmacy
	   • Quality of fax image
	•Delays in member service / care
	•If not shredded, original prescription could be filled at another KP pharmacy (high diversion potential)

Sample Controlled New Medication Order Fax Form (plain paper prescription)*

Held KPHC order printed from pharmacy system*

Sample For Board of Pharmacy Presentation Purpose Only. (All prescriber, pharmacy, medication and patient information in italics is not real and is printed on demand from the KP electronic Health Record.)
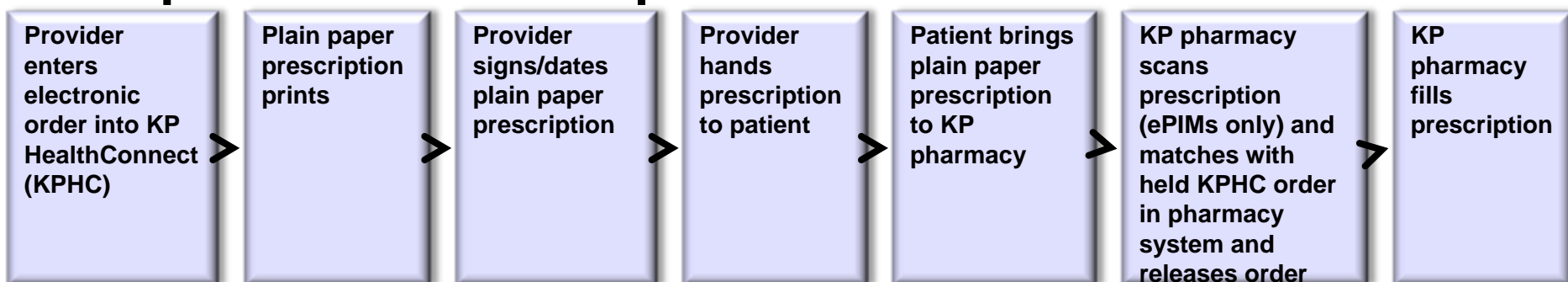
Reviewed and not recommended (see appendix):

- **Option #1: Verbal Order**

- **Option #2: Secure On Demand Printing**

- **Option #3: Personalized secure paper prescription**

Recommended option:

Option #4: Plain paper prescription

▪ Option #4 – Plain Paper

| Provider enters electronic order into KP HealthConnect (KPHC) | > | Plain paper prescription prints | > | Provider signs/dates plain paper prescription | > | Provider hands prescription to patient | > | Patient brings plain paper prescription to KP pharmacy | > | KP pharmacy scans prescription (ePIMs only) and matches with held KPHC order in pharmacy system and releases order | > | KP pharmacy fills prescription |

Advantages	Disadvantages
Are we Compliant? •Compliant with current federal and state requirements for prescription content **Is it Accurate?** •Plain paper prescription matches KPHC electronic order •Assures medical and prescription record is complete in KPHC **Is it Timely / Efficient?** •No faxing in medical office / clinic; no receiving of fax and printing of KPHC order to match fax in pharmacy	**Are there Additional Steps?** •No significant additional workflow steps for either provider or pharmacy **Are there other Issues?** •Would require Personalized Secure Prescription blank if member went to non–KP pharmacy; or verbal order to non-KP pharmacy •Education of inspectors •Patient may lose prescription paper

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Sample Plain Paper
Prescription Order*

Schedule III-V Medication Fax Prescription

Prescriber's Office Address and Department
MEDICINE
1200 El Camino Real
South San Francisco, CA 94080-3208
Dept: 650-742-2100
Main: 650-742-2000

Patient Information

Mouse, Mickey,M   Med Rec #   [110012950544]   DOB   05/20/1989   Female
1005 SAN FRAN STREET   Home Phone   415-123-4567
SAN FRANCISCO, CA 94115   Work Phone   415-123-4567

Medication	Quantity	Refills	Start	End
VICOPROFEN 7.5-200 MG ORAL TAB *60*		*0/0*	*7/22/2010*	

Sig: *TAKE 1 TABLET ORALLY 2 TIMES A DAY*
Route: *Oral*
Non-formulary Exception Code: *N/A*
Class: *Fill Now*
Order #: *153385820*

Prescriber
Signature: _____*Stanley Permanente*_____ Date: _2/22/13_____ NPI # _____
Do Not Substitute ____ Do Not Change Refill Quantity _____ Do Not Change Dosage Form_____
Prescriber Name, License: *Stanley Permanente (M.D.),AA124*
DEA#:   *AA3121403*

For Schedule III, IV, and V Controlled Substances, this prescription is valid ONLY at a *Kaiser Permanente, Kaiser Foundation Health Plan* or *Kaiser Foundation Hospital Pharmacy* with a matching electronic Kaiser medical record order.
For filling a Schedule III, IV & V controlled substance prescription at a non-*Kaiser* pharmacy, the patient should ask the prescriber for a Secure Prescription Blank or the pharmacy may phone the prescriber.

*Sample For Board of Pharmacy Presentation Purpose Only

(All prescriber, pharmacy, medication and patient information in italics is not real and is printed on demand from the KP electronic Health Record.)

Valid Controlled Substance Prescription Requirements for Written Prescriptions

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Regulatory Agent	Prescription Paper Requirements
DEA	Plain Paper with key content*and hand signed and hand dated in ink by a prescriber with a DEA registration appropriate to the Schedule of the medication.
CA Board of Pharmacy	Paper type acceptable to the CA DOJ with the key content*
CA Department of Justice	Paper with defined Security features I** from a DOJ approved vendor that meets DEA and BoP content* requirements

*Key Content: Prescriber's name, license category, address and phone #, DEA # & State License #; Patient's Name and Address, Refill information (if any),drug name, quantity, strength and the directions for its use plus, if requested by the patient, the Purpose or Condition for which the drug was prescribed,. [CA H&S Code 11164, & 11165; CA B&P Code 4040]

**Latent "Void" prints if scanned/photocopied, DOJ defined watermark, chemical void protection, thermochromic ink feature, disappearing opaque writing, description of security features, 6 quantity range boxes, defined number of prescriptions statement, box for # of refills, printer company identification, Pad lot # and sequence # of blank.

Valid Controlled Substance Prescription Requirements for Written Prescriptions

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Kaiser Permanente (KP) Difference

- **KP is a *closed* system of prescribers and pharmacies sharing an electronic medical record and a pharmacy system that reports all pharmacy dispensing back to its KP prescribers.**

- **KP is a comprehensive care, prepaid medical care organization ultimately responsible for the care outcomes of all of its Members.**

- **KP has a 70+ year excellent reputation for providing *High Quality, Affordable Care* in California with currently over 6 million Members in California.**

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- ## **Option #4**
  - ### **Patients Wishing to Use Non-KP Pharmacy**
    - Plain paper prescription has printed statement:
      - "Valid for dispensing <u>only</u> at a Kaiser Permanente pharmacy with an approved electronic order in KP Health Connect." Patient may request a written prescription from their provider if he/she desire to fill at a non-KP pharmacy."
    - Provider should determine if member will fill at a non-KP pharmacy and issue personalized secure paper prescription.
    - If a patient presents plain paper prescription at non-KP pharmacy, pharmacist should call prescriber for verbal order.

Benefits Summary for Recommended Interim Workflow (Option #4)

- **KP Staff & Member Benefits**
  - Assures complete electronic medical and prescription records in KPHC
  - Simplified clinic and pharmacy processes (eliminates faxing)
  - Minimizes delay in service and care provision

- **Compliance Benefits**
  - Compliant with all applicable DEA, DOJ and BOP requirements for prescription content

- **Fraud, Waste, and Abuse Benefits**
  - Hard copy always matches KPHC order; otherwise, prescription not filled and then prescriber contacted
  - Eliminates signed original prescription diversion potential under current fax to pharmacy workflow process.

Appendix

Appendix Agenda
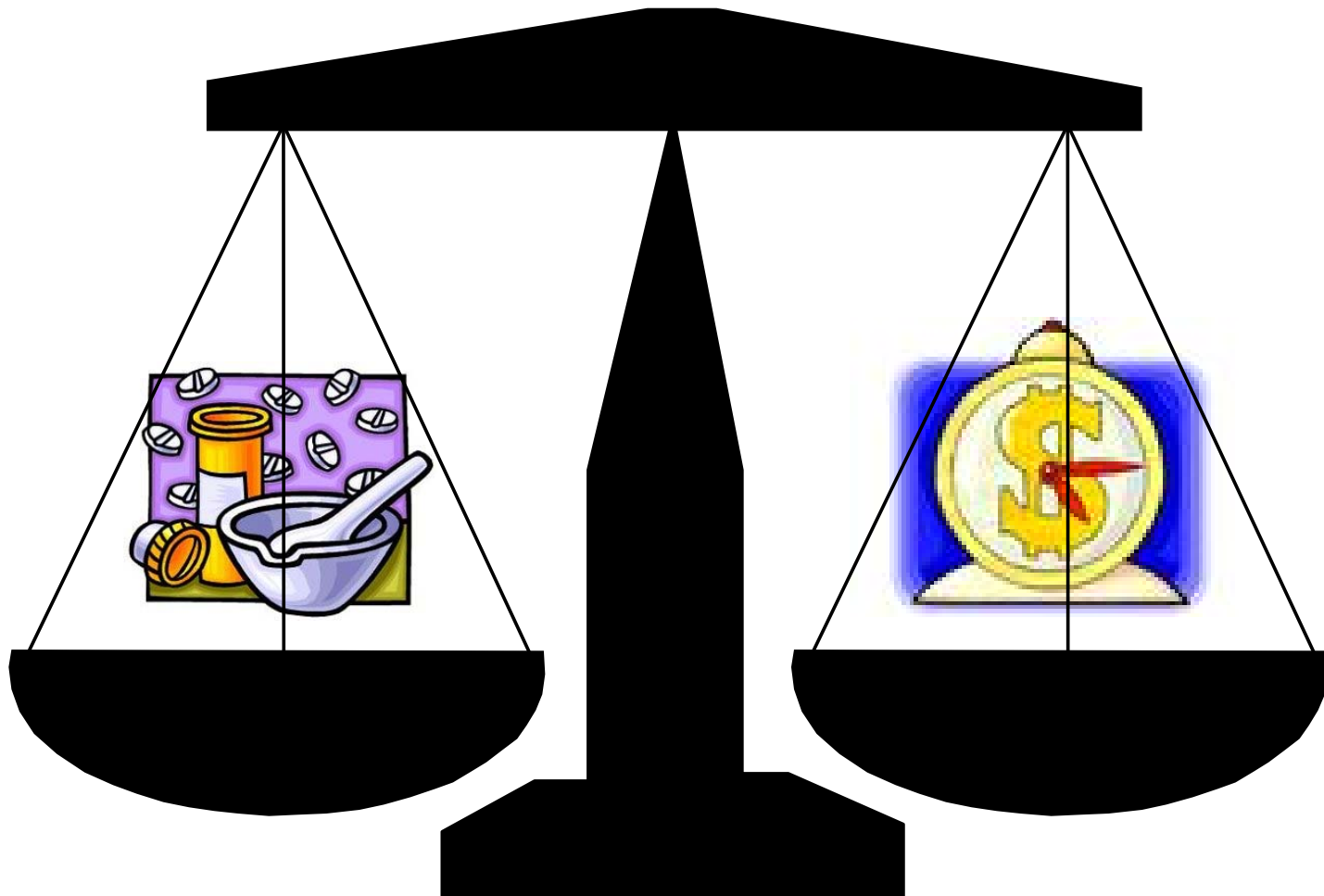
- **Option #1 – Verbal Orders**

- **Option #2: Secure On Demand Printing**

- **Option #3 – Personalized Secure Prescription Pad**

- **Option #4 Recommended Interim Workflow**

Option #1: Verbal Orders
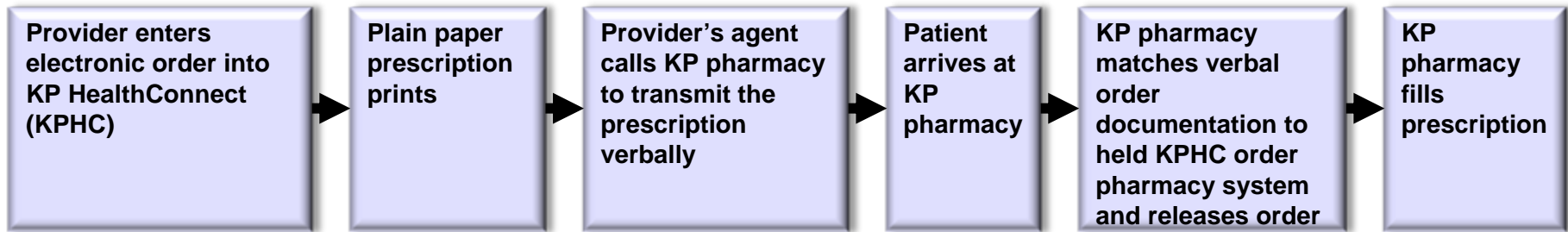
```
Provider enters        Plain paper        Provider's agent       Patient         KP pharmacy          KP
electronic order into  prescription       calls KP pharmacy      arrives at      matches verbal       pharmacy
KP HealthConnect       prints             to transmit the        KP              order                fills
(KPHC)                                    prescription           pharmacy        documentation to     prescription
                                          verbally                               held KPHC order
                                                                                 pharmacy system
                                                                                 and releases order
```

Key Considerations

Are we Compliant?
• Compliant with current federal and state requirements

Is it Accurate?
• Potential for provider agent transmission error
  • Verbal order may not match KPHC electronic order
• Potential for transcription errors by RPh

Is it Timely / Efficient?
• No faxing
• Nurse not waiting for MD signature
• Significant provider agent and pharmacist resources required to call in and receive prescriptions

Are there Additional Steps?
• Requires additional phone call from provider agent to transmit and for pharmacist to receive each patient's prescription (s)
• Pharmacist must document each prescription manually

Are there other Issues?
• Patient arrives prior to phone call (Pharmacy calls backs to MD / Clinic office)
• Busy signals at the pharmacy (requires provider, nurse or provider agent call backs)
• Interruption of clinic and pharmacy work flow (increased chance of errors)
• Delays in member service / care

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KPHC Order Printout for Verbal order transmission*

KP Pharmacist Documentation of Verbal Order*

Sample For Board of Pharmacy Presentation Purpose Only. (All prescriber, pharmacy, medication and patient information in italics is not real and is printed on demand from the KP electronic Health Record.)

Option #2: SecureOnDemand Printing
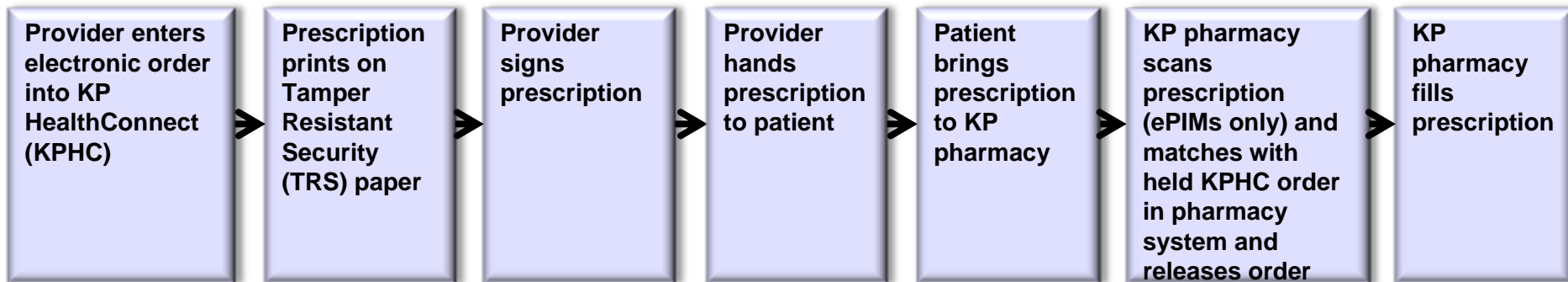
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| Provider enters electronic order into KP HealthConnect (KPHC) | → | Prescription prints on Tamper Resistant Security (TRS) paper | → | Provider signs prescription | → | Provider hands prescription to patient | → | Patient brings prescription to KP pharmacy | → | KP pharmacy scans prescription (ePIMs only) and matches with held KPHC order in pharmacy system and releases order | → | KP pharmacy fills prescription |

Key considerations

Are we Compliant?
• Compliant with current federal and state requirements

Is it Accurate?
• Tamper Resistant Security (TRS) paper prescription matches KPHC electronic order
• Assures medical and prescription record is complete in KPHC

Is it Efficient?
• No faxing in medical office / clinic; no receiving of fax and printing of KPHC order to match fax in pharmacy

Are there Additional Steps?
• No significant additional workflow steps for either provider or pharmacy

Are there other Issues?
• Expense to acquire and implement <u>thousands</u> of secure printers at clinics
• Not a quick solution; (approval, purchase, set up, installation, training, provisioning of users)
• Dramatically increases number of blank secure paper forms and thereby increases risk of diversion
• Physical security of printer and TRS paper within must be maintained.
• BOP requires dedicated physician accountable for assuring security of TRS paper supply and printers
• Education of inspectors
• Patient may lose prescription form

Option #2: SecureOnDemand Printer and sample prescription printout

Secure OnDemand Printer

Sample Prescription Printout*

Sample For Board of Pharmacy Presentation Purpose Only. (All prescriber, pharmacy, medication and patient information in italics is not real and is printed on demand from the KP electronic Health Record.)

Option #3 – Personalized Secure Prescription Pad
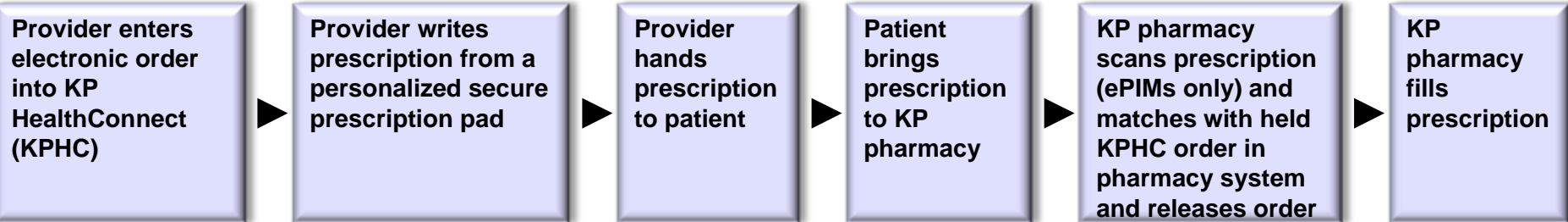
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Provider enters electronic order into KP HealthConnect (KPHC)	Provider writes prescription from a personalized secure prescription pad	Provider hands prescription to patient	Patient brings prescription to KP pharmacy	KP pharmacy scans prescription (ePIMs only) and matches with held KPHC order in pharmacy system and releases order	KP pharmacy fills prescription

Key considerations

Are we Compliant?
• Compliant with current federal and state requirements

Is it Accurate?
• Tamper Resistant Security paper prescription may not match KPHC electronic order
• Does not assures medical and prescription record is complete in KPHC

Is it Timely / Efficient?
• No faxing in medical office / clinic; no receiving of fax and printing of KPHC order to match fax in pharmacy
• Additional significant manual step for provider to prepare each prescription manually

Are there Additional Steps?
• Additional significant manual step for provider to prepare prescription manually

Are there other Issues?
• Dramatically increases number of personalized secure prescription pads and thereby increases risk of diversion
• Patient may lose prescription form

Sample Personalized Secure Prescription Pad*

Sample For Board of Pharmacy Presentation Purpose Only. (All prescriber, pharmacy, medication and patient information in italics is not real and is printed on demand from the KP electronic Health Record.)

Recommended Workflow for Controlled Substance Prescriptions CIII-V (Waiters – Patients in Pharmacy)

CALIFORNIA BOARD OF PHARMACY ENFORCEMENT COMMITTEE
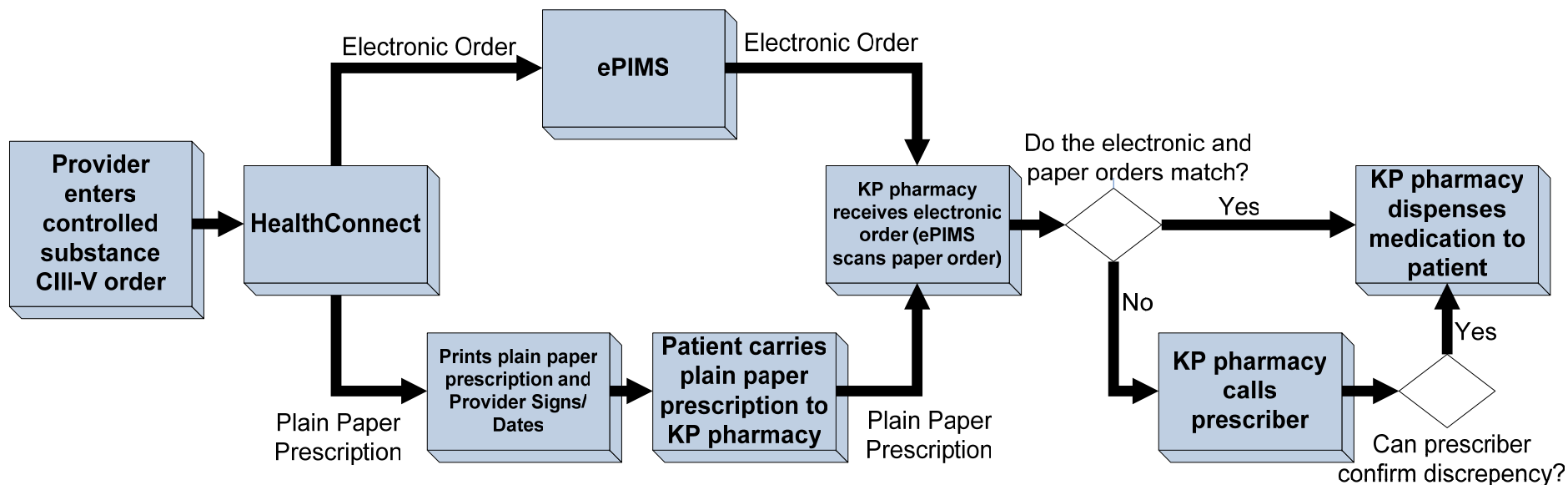
GS1 TRACK AND TRACE STANDARDS AND IMPLEMENTATION

CONTENTS

- Update on Standards

- Guideline Development

- Activities to support industry in preparing for 2015

GS1 STANDARDS

THE ROLE OF GS1

GS1 is a not-for-profit organisation dedicated to the design and implementation of **global standards** to improve the efficiency and visibility of **supply chains** globally and across sectors

- **109** member service organizations
- **35** years of experience
- **Neutral** platform for all supply chain stakeholders
- Over a **million** companies doing business across **150** countries
- Over **6 billion** transactions a day

GS1 is the most widely used supply chain standards system in the world

GS1 IS BOTH GLOBAL & LOCAL

GS1 Global Office

Identification, creation, development and maintenance of standards and our foundational architecture, coordination with other international bodies, development of training programs...not-for profit organization …

GS1 Member Organizations

Local offices in 110 + countries around the globe, such as **GS1 US**
Implementation of standards, local regulatory adjustments, community management and relationship management with local governments and regulatory agencies...

THE GLOBAL LANGUAGE
OF BUSINESS

GS1 STANDARDS

GS1 Standards for identifying, capturing, and sharing information - about products, business locations, and more - make it possible for companies to speak the same language, connect with each other, and move their business forward.

IDENTIFY   CAPTURE   SHARE

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GS1 STANDARDS IN HEALTHCARE

IDENTIFY: GS1 SYSTEM IDENTIFICATION NUMBERS

GLN Global Location Number   **GTIN®** Global Trade Item Number®   **SSCC** Serial Shipping Container Code   **EPC®** Electronic Product Code™

GLN	GTIN	GTIN / SSCC	SSCC		GLN		SSCC	GLN		GTIN / SSCC	GTIN	GLN	
MANUFACTURER	ITEM	CASE	PALLET	TRANSPORT	DISTRIBUTOR	TRANSPORT	PALLET	DISTRIBUTION CENTER	TRANSPORT	CASE	ITEM	HEALTHCARE PROVIDER	PATIENT

CAPTURE: GS1 SYSTEM DATA CARRIERS

BARCODES   **EPC-ENABLED RFID TAGS**

EAN/UPC

6 14141 98765 8

GS1-128

(01) 0 06141 41 987658

ITF-14

2 06 14141 98765 2

GS1 DataBar™

(01) 0 06141 41 987658

GS1 DataMatrix

(01) 00614141987658
(17) 120831
(10) A1B2C3D4E5
(21) 00098522

SHARE: GS1 INTERFACE STANDARDS FOR ELECTRONIC COMMERCE

MASTER DATA GLN Registry for Healthcare®, Global Data Synchronization Network™ (GDSN®)   **TRANSACTIONAL DATA** eCom/EDI   **PHYSICAL EVENT DATA** EPC Information Services

◄——————————————— INTEROPERABILITY ———————————————►

| ITEM DATA | LOCATION DATA | PURCHASE ORDER | SHIPPING NOTICE | INVOICE | PRODUCT RECALL/WITHDRAWAL | PEDIGREE | TRACK & TRACE |

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GS1 STANDARDS IN HEALTHCARE

ITEM	CASE	PALLET
Barcodes Carries a Global Trade Item Number® (GTIN®)	**ITF-14** Carries a GTIN	**ITF-14** Carries a GTIN

ITEM

EAN/UPC

GS1-128

(01) 0 0614141 987658

GS1 DataMatrix

(01) 00614141987658
(21) 00098522

GS1 DataBar™

(01) 0 0614141 987658

OR

EPC®-ENABLED RFID
Carries a Serialized GTIN (SGTIN)

CASE

2 06 14141 98765 2

OR

GS1-128
Carries a GTIN with extended data or a
Serial Shipping Container Code (SSCC)

(01) 2 0614141 98765 2 (10) A1B2C3002

AND

EPC-ENABLED RFID
Carries an SGTIN or SSCC

PALLET

5 06 14141 98765 3

OR

GS1-128
Carries a GTIN or an SSCC

(00) 0 0614141 0000098765 8

AND

EPC-ENABLED RFID
Carries an SGTIN or SSCC

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APPLYING GS1 STANDARDS TO SERIALIZATION AND PEDIGREE

SECURE SUPPLY CHAIN TASK FORCE
IMPLEMENTATION GUIDELINE

GS1 HEALTHCARE US

IMPLEMENTATION GUIDELINE

Applying GS1 Standards to
U.S. Pharmaceutical Supply Chain Business Processes
TO SUPPORT PEDIGREE AND TRACK & TRACE

Release 1.0 (February, 2013)

www.gs1us.org/RxGuideline

Contents of v1.0:

- Identifying Trade Units (Products, Cases, and Kits):
- Identifying Logistics Units (Cases, Pallets, and Totes)
- Identifying Parties & Locations
  Encoding GS1 Data Carriers
- Translating Captured Data
- Master Data Management (product and location)
- Applying GS1 Standards for Event Data
- Supply Chain Events to be Captured for Pedigree

Continuing work on v2.0

- Exceptions Processing
- Pilot learnings / best practices
- Forward Logistics Examples
- Reverse Logistics Examples
- Potential Architectural Models

4. Background Concepts

4.1. Relationship between NDC – GTIN – SGTIN

The FDA National Drug Code (NDC) is a <u>U.S. regulatory identifier</u> used to identify pharmaceutical products for regulatory purposes. The GTIN is a <u>supply chain identifier</u> used to identify *products* for supply chain purposes. The SGTIN is a <u>supply chain identifier</u> used to identify *individual instances of a product* for supply chain purposes. There is a cohesive, hierarchical relationship between these identifiers. As illustrated in Figure 1, NDCs can be embedded into GTINs so that identification of pharmaceutical products for supply chain purposes is consistent with identification of pharmaceutical products for regulatory purposes. GTINs can then be supplemented with serial numbers to identify individual instances of the pharmaceutical product.

NDC	1234567890
GTIN	00312345678906
SGTIN	00312345678906 101

Figure 1: Relationship of the NDC, GTIN and SGTIN

4.2. NDC Labeler Code & GS1 Company Prefix

The NDC is a 10-digit identifier comprising two segments: a *Labeler Code* assigned by the FDA and a *Product/Package Code* assigned by the manufacturer. The *Labeler Code* is a variable length identifier assigned by the FDA (and encoded into NDCs) to identify a company that manufactures a drug (including repackers or relabelers) or distributes a drug (under its own name).

GS1 US has reserved a placeholder in the GS1 Company Prefix numbering system that enables the NDC *Labeler Code* to be integrated into the GS1 Company Prefix for pharmaceutical companies. The placeholder (named the "GS1 Prefix") is 03, and the GS1 Company Prefix for a pharmaceutical company is simply its *Labeler Code* with "03" appended in front. For example:

GS1 Prefix	03
FDA-assigned *Labeler Code*	61414
GS1 Company Prefix	0361414

4.3.   Integrating NDCs into GTINs

As noted above, NDCs can be integrated into GTINs. Figure 2 illustrates how the two NDC segments (i.e., *Labeler Code* and *Product/Package Code*) are integrated into the segments of a GTIN-14. The NDC *Labeler Code* is integrated into a GS1 Company Prefix (as described above). The NDC *Product/Package Code* is used to populate the Item Reference segment of the GTIN.

0 0 3 6 1 4 1 4 5 6 7 8

Position 1 — Indicator Digit

Position 2 – Position 13

GS1 Company Prefix + Item Reference

Position 14 — Check Digit

03 + FDA Labeler Code

NDC Product/Package

Figure 2: Segments of a GTIN-14 that embeds an NDC (based on the hypothetical GTIN "00361414567894")

4.4.   Assigning vs. Storing vs. Encoding GTINs

GTINs can be assigned as 8 digits, 12 digits, 13 digits, or 14 digits in length. Within the U.S. pharmaceutical supply chain, the 12-digit GTIN ("GTIN-12") and the 14-digit GTIN ("GTIN-14") are predominantly used. Regardless of how they are assigned, it is important to understand that GTINs are always encoded in barcodes and stored in databases in 14-digit format.
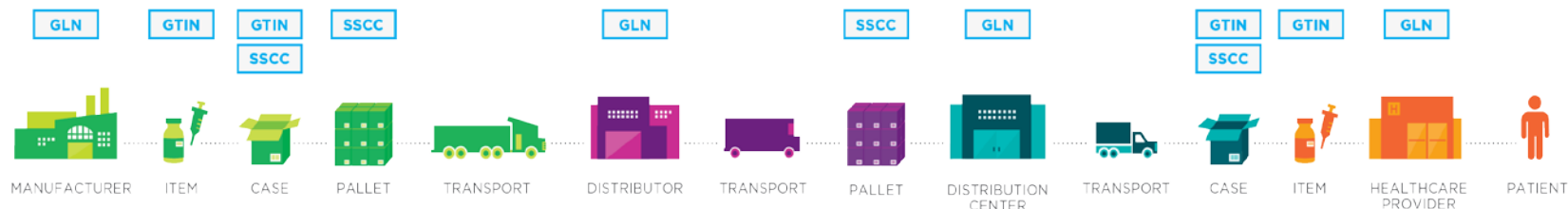
GS1 STANDARDS IN HEALTHCARE

IDENTIFY: GS1 SYSTEM IDENTIFICATION NUMBERS

GLN Global Location Number   **GTIN®** Global Trade Item Number®   **SSCC** Serial Shipping Container Code   **EPC®** Electronic Product Code™

| GLN | GTIN | GTIN SSCC | SSCC | | GLN | | SSCC | GLN | | GTIN SSCC | GTIN | | GLN |

MANUFACTURER — ITEM — CASE — PALLET — TRANSPORT — DISTRIBUTOR — TRANSPORT — PALLET — DISTRIBUTION CENTER — TRANSPORT — CASE — ITEM — HEALTHCARE PROVIDER — PATIENT

CAPTURE: GS1 SYSTEM DATA CARRIERS

BARCODES   **EPC-ENABLED RFID TAGS**

EAN/UPC   GS1-128   ITF-14   GS1 DataBar™   GS1 DataMatrix

6 14141 98765 8   (01) 0 0614141 987658   2 06 14141 98765 2   (01) 0 0614141 987658

(01) 00614141987658
(17) 120831
(10) A1B2C3D4E5
(21) 00098522

SHARE: GS1 INTERFACE STANDARDS FOR ELECTRONIC COMMERCE

MASTER DATA GLN Registry for Healthcare®, Global Data Synchronization Network™ (GDSN®) **TRANSACTIONAL DATA** eCom/EDI **PHYSICAL EVENT DATA** EPC Information Services

← INTEROPERABILITY →

ITEM DATA   LOCATION DATA   PURCHASE ORDER   SHIPPING NOTICE   INVOICE   PRODUCT RECALL/WITHDRAWAL   PEDIGREE   TRACK & TRACE

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GS1 STANDARDS IN HEALTHCARE

IDENTIFY: GS1 SYSTEM IDENTIFICATION NUMBERS

GLN Global Location Number   **GTIN®** Global Trade Item Number®   **SSCC** Serial Shipping Container Code   **EPC®** Electronic Product Code™

GLN	GTIN	GTIN / SSCC	SSCC		GLN		SSCC	GLN		GTIN / SSCC	GTIN	GLN	
MANUFACTURER	ITEM	CASE	PALLET	TRANSPORT	DISTRIBUTOR	TRANSPORT	PALLET	DISTRIBUTION CENTER	TRANSPORT	CASE	ITEM	HEALTHCARE PROVIDER	PATIENT

CAPTURE: GS1 SYSTEM DATA CARRIERS

BARCODES   **EPC-ENABLED RFID TAGS**

EAN/UPC   GS1-128   ITF-14   GS1 DataBar™   GS1 DataMatrix

6 14141 98765 8

(01) 0 0614141 987658

2 06 14141 98765 2

(01) 0 0614141 98765 8

(01) 00614141987658
(17) 120831
(10) A1B2C3D4E5
(21) 00098522

SHARE: GS1 INTERFACE STANDARDS FOR ELECTRONIC COMMERCE

MASTER DATA GLN Registry for Healthcare®, Global Data Synchronization Network™ (GDSN®)   **TRANSACTIONAL DATA** eCom/EDI   **PHYSICAL EVENT DATA** EPC Information Services

INTEROPERABILITY

ITEM DATA   LOCATION DATA   PURCHASE ORDER   SHIPPING NOTICE   INVOICE   PRODUCT RECALL/WITHDRAWAL   PEDIGREE   TRACK & TRACE

Part 2: Identify

GS1 Identification Numbers globally and uniquely identify supply chain objects (e.g., products, assets, logistic units, etc.), as well as supply chain partners and physical locations. Table 3 lists the GS1 identification standards used in this guideline to support pedigree and track and trace.

Supply Chain Object or Location	Corresponding GS1 Identifier	Instance
Companies and warehouses	GLN	
Specific locations within companies & warehouses	GLN + extension	
Item	GTIN	GTIN + serial number
Kit	GTIN	GTIN + serial number
Homogeneous Case	GTIN	GTIN + serial number, SSCC
Mixed / Partial Case		SSCC
Pallet		SSCC
Tote		SSCC

Table C: GS1 Identifiers[1]

[1] There may be other layers of packaging that are not specified here.

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IDENTIFY

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5. Identifying Trade Units (Products, Cases and Kits): GTIN

In the GS1 System, products, cases and kits[2] are identified with the Global Trade Item Number (GTIN). GTIN is a globally unique, standards-based, identification number for trade items. When a manufacturer assigns ("allocates") a GTIN, they define a prescribed set of data about the product to which that GTIN relates. These *product description attributes* define master data that is consistent across all instances of the product (e.g., size; color; brand information; etc.). GS1 Standards specify the list of attributes that must be defined for each GTIN, as well as the permissible values. Once the GTIN is allocated and the attributes are defined, the GTIN and its associated attributes are then saved in a database (like a GDSN-certified Data Pool) and shared among supply chain partners. (The section of this guideline entitled "Master Data Management" explains how this information can be combined with EPCIS event information to obtain supply chain visibility.)

(NOTE: *GS1 US provides an online tool, known as Data Driver®, to support users in allocating GTINs and defining the associated attributes.* Visit http://www.gs1us.org/resources/tools/data-driver *for more information.*)

5.1. Assigning GTINs

GTINs can be assigned as 8 digits, 12 digits, 13 digits, or 14 digits in length (known as GTIN-8, GTIN-12, GTIN-13 and GTIN-14, respectively). However, within the U.S. pharmaceutical supply chain, the GTIN-12 and the GTIN-14 are predominantly used. The choice of format is related to point of sale:

- **Assign a GTIN-12** to pharmaceuticals products that will be scanned at point of sale (see *Section 4.5* for more information)

- **Assign a GTIN-14** to pharmaceuticals that will not be scanned at point of sale

5.1.1. Creating a GTIN-12

Each GTIN-12 is a numerical string comprising three distinct segments. The three segments within a GTIN-12 are:

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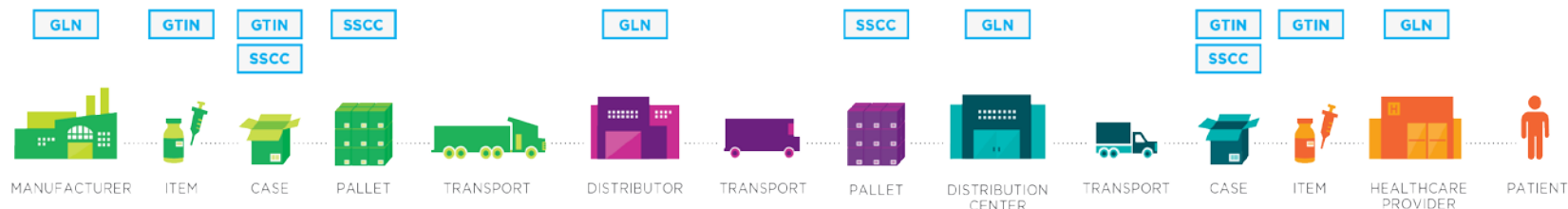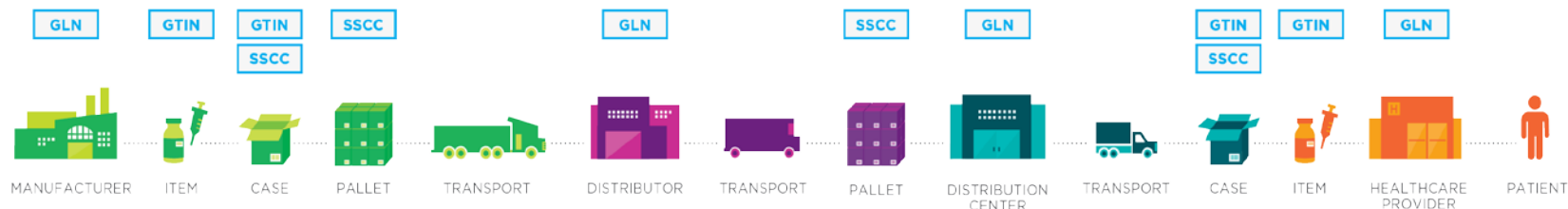
IDENTIFY: GS1 SYSTEM IDENTIFICATION NUMBERS

GLN Global Location Number   **GTIN®** Global Trade Item Number®   **SSCC** Serial Shipping Container Code   **EPC®** Electronic Product Code™

MANUFACTURER — ITEM — CASE — PALLET — TRANSPORT — DISTRIBUTOR — TRANSPORT — PALLET — DISTRIBUTION CENTER — TRANSPORT — CASE — ITEM — HEALTHCARE PROVIDER — PATIENT

CAPTURE: GS1 SYSTEM DATA CARRIERS

BARCODES   **EPC-ENABLED RFID TAGS**

EAN/UPC

6 14141 98765 8

GS1-128

(01) 0 0614141 987658

ITF-14

2 06 14141 98765 2

GS1 DataBar™

(01) 0 0614141 987658

GS1 DataMatrix

(01) 00614141987658
(17) 120831
(10) A1B2C3D4E5
(21) 00098522

SHARE: GS1 INTERFACE STANDARDS FOR ELECTRONIC COMMERCE

MASTER DATA GLN Registry for Healthcare®, Global Data Synchronization Network™ (GDSN®)   **TRANSACTIONAL DATA** eCom/EDI   **PHYSICAL EVENT DATA** EPC Information Services

← INTEROPERABILITY →

ITEM DATA   LOCATION DATA   PURCHASE ORDER   SHIPPING NOTICE   INVOICE   PRODUCT RECALL/WITHDRAWAL   PEDIGREE   TRACK & TRACE

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Part 3: Capture

GS1 Data Carriers provide *machine-readable representations* of GS1 Identification Numbers that facilitate automatic identification and data capture. In order to accommodate a variety of environments and applications, the GS1 System supports eight data carriers: six barcode symbologies (i.e., GS1 Barcodes) and two RFID tags (i.e., GS1 EPC/RFID Tags).

Table 7 lists the GS1 data carriers used in this guideline to support pedigree and track and trace. Because this guideline documents a specific application of the standards to support serialization and pedigree, only data carriers that can carry serial numbers are shown.

Supply Chain Object	GS1 Data Carrier Options
TRADE ITEMS: Products, Cases & Kits	GS1 DataMatrix
	GS1-128
	EPC/RFID Tag
LOGISTICS UNITS: Cases, Pallets & Totes	GS1-128
	GS1 DataMatrix
	EPC/RFID Tag

Table G: GS1 Data Carriers Used in this Guideline

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CAPTURE

AI (01)	GTIN	AI (21)	Serial Number
AI (00)	SSCC	AI (10)	Batch/Lot Number
AI (414)	GLN (physical location)	AI (17)	Expiration Date
AI (254)	GLN Extension		

More than one AI can be carried in one barcode. Table 8 presents some high-level concepts and principles that should be followed when encoding barcodes.

Principle	Example/Illustration
Each barcode data element has a two- to four-digit AI that defines data type and field size.	GTIN — AI(01) Serial Number — AI(21) Batch/Lot Number — AI(10) Expiration Date — AI(17) SSCC — AI (00)
When encoding, each data element is preceded by its corresponding AI.	GTIN — (01)00314141999995 Expiration Date — (17)101231 Batch/Lot Number — (10)987654321GFEDCBA Serial Number — (21)ABCDEFG123456789 SSCC — (00)003345678912345604
Encode the GS1 Identifier (GTIN or SSCC) first. Encode any optional data (such as batch/lot number, expiration date, serial number, etc.) following the identifier. NOTE: *Although parentheses and spaces appear in the human readable text accompanying the barcode, these characters are not encoded in the barcode itself.*	 (01) 00314141999995 (10) 987654321GFEDCBA
For the most efficient encoding, ensure that fixed- length AI's precede variable-length AI's.	 (01) 00314141999995 (17) 101231 (10) 987654321GFEDCBA (21) 123456789ABCDEFG GTIN *fixed* Expiration Date *fixed* Batch/Lot Number *variable* Serial Number *variable*

AI (01)	GTIN	AI (21)	Serial Number
AI (00)	SSCC	AI (10)	Batch/Lot Number
AI (414)	GLN (physical location)	AI (17)	Expiration Date
AI (254)	GLN Extension		

More than one AI can be carried in one barcode. Table 8 presents some high-level concepts and principles that should be followed when encoding barcodes.

Principle	Example/Illustration
Each barcode data element has a two- to four-digit AI that defines data type and field size.	GTIN — AI(01) Serial Number — AI(21) Batch/Lot Number — AI(10) Expiration Date — AI(17) SSCC — AI (00)
When encoding, each data element is preceded by its corresponding AI.	GTIN — (01)00314141999995 Expiration Date — (17)101231 Batch/Lot Number — (10)987654321GFEDCBA Serial Number — (21)ABCDEFG123456789 SSCC — (00)003345678912345604
Encode the GS1 Identifier (GTIN or SSCC) first. Encode any optional data (such as batch/lot number, expiration date, serial number, etc.) following the identifier. NOTE: *Although parentheses and spaces appear in the human readable text accompanying the barcode, these characters are not encoded in the barcode itself.*	(01) 00314141999995 (10) 987654321GFEDCBA
For the most efficient encoding, ensure that fixed- length AI's precede variable-length AI's.	(01) 00314141999995 (17) 101231 (10) 987654321GFEDCBA (21) 123456789ABCDEFG GTIN *fixed* Expiration Date *fixed* Batch/Lot Number *variable* Serial Number *variable*

ⓘ Marking Products with Both UPC-A and GS1 DataMatrix

Many pharmaceutical manufacturers are marking products that move through a Point of Sale (POS) with both a UPC-A and a GS1 DataMatrix:

- Any item that passes through a POS is typically marked with a UPC-A. The UPC-A is a linear barcode that holds a maximum of 12 digits, which promotes readability by traditional POS systems. The UPC-A can be used to satisfy the FDA's linear barcode requirement. However, because it is limited to 12 digits, the UPC-A cannot carry the information needed to satisfy serialization and/or pedigree requirements.

- The GS1 DataMatrix is a 2D barcode that can carry more data (e.g., GTIN, serial number, expiration date, etc.) in a smaller space. Most manufacturers are choosing to use the GS1 DataMatrix to satisfy serialization and/or pedigree requirements. However, as a 2D barcode, the GS1 DataMatrix does not satisfy the FDA's linear barcode requirement.

Marking pharmaceutical products that cross POS with both barcodes satisfies both types of requirements (i.e., the UPC-A for the FDA linear barcode requirement, and the GS1 DataMatrix for serialization/pedigree requirements). To ensure that the GTIN encoded in both barcodes is the same, manufacturers should follow the recommendations outlined in Section 4.5 for all products that will be marked with both a UPC-A and a GS1 DataMatrix.

3 14141 99999 5

GTIN-12 encoded in a UPC-A

(01) 00314141999995

GTIN-12 encoded in a GS1 DataMatrix

8.1.2. Logistics Units: Pallets, Cases & Totes

This guideline includes two barcode options for pallets, cases and totes: GS1-128 and GS1 DataMatrix. There one required data element to be encoded: SSCC.

Cases Pallets & Totes		
Required Identification Information	Data Element	Corresponding GS1 Standard
	SSCC	AI (00)
GS1 Barcode Options	GS1-128 GS1 DataMatrix	

Table J: Barcodes for Pallets, Cases & Totes

Encoding Principles:

SSCC
- The two-digit AI (00) is used to indicate SSCC.
- A fixed-length field comprising the 18 numeric characters of SSCC data follows the AI.
- The data syntax for the SSCC component is n2 + n18.
- **EXAMPLE: 00003345678912345604**

Examples:

Figure 12: SSCC Encoded in a GS1-128

(00) 0 0314141 000098765 7

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Part 4: Share Concepts

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The data elements captured and recorded for each EPCIS are presented in Table 13 below.

Dimension	Data	Definition	Examples
	Event Type Action	the event type and the action together define the type of EPCIS event; e.g., object creation, object observation, aggregation, disaggregation, etc	Object Event with Action = ADD Aggregation Event with Action = DELETE etc.
What	EPC List	the item's GS1 Identification Key, expressed as an EPC Pure Identity URI. Depending on the event type, this will either be a list of EPCs, or the combination of a Parent ID and a list of child EPCs	GTIN, SSCC, GRAI, etc.
	Parent ID		
	Child EPCs		
When	Event Time	the moment in time at which the event occurred	March 15, 2010 at 10:07am UTC
	Event Timezone Offset	indicates the local time zone in effect at the place where the event occurred. This is not needed to interpret Event Time (which carries its own timezone indicator) but instead helps software display data to users in local time	UTC -05:00
Where	Read Point	the location at which the event took place, expressed as an EPC Pure Identity URI	GLN or GLN with extension
	Business Location	the location at which the objects are presumed to be following the event until a subsequent event says otherwise, expressed as an EPC Pure Identity URI	GLN or GLN with extension
Why	Business Step	the business process taking place at the time of this event	Shipping, Receiving, Picking, etc.
	Disposition	business condition of the objects named in the what dimension that is presumed to hold until a subsequent event occurs	Saleable, Recalled, etc.
	Business Transaction	one or more references to associated business transactions, each comprised of a business transaction type (e.g., purchase order, invoice, etc) and a globally unique reference to a specific transaction of that type	Acme Corp Purchase Order #1234

Table M: EPCIS Data

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Figure 16 below shows the relationships of *Event Times*. The "≤" symbol indicates that the first *Event Time* must be strictly less than the second *Event Time*.

Figure 16: Event Time Relationships for Pedigree Purposes

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17.1. Commissioning

Commissioning is the process of associating an object (e.g., bottle, case, tote, pallet, etc.) with an EPC (i.e., an identifier representing a GTIN / Serial Number, SSCC, etc.). The EPC may be encoded in a data carrier (i.e., a barcode or EPC/RFID tag) and applied to the object during this step, or the data carrier may have been previously encoded.

❖ **A Commissioning event shall be an EPCIS Object Event populated as follows:**

Element	Usage	Type	Value	Reason
eventTime	Required	Timestamp	Date and time of event (see Section 14.1).	EPCIS standard definition
recordTime	Optional	Timestamp	(Optional) Date and time the event was recorded in an EPCIS repository.	EPCIS standard definition
eventTimeZoneOffset	Required	String	Time zone offset in effect at the time and place where the event occurred.	EPCIS standard definition
epcList	Required	List of URI	EPC(s) of the commissioned item in EPC Pure Identity URI format. If more than one EPC is included, they shall all have the same value for extensions defined below, or shall all require these extensions to be omitted. EPCs having different values for these extensions must be shared in different Commissioning events.	Because the extensions below are *event-level* extensions, they must be the same for all EPCs in the event.
action	Required	String	ADD	EPCIS standard definition
bizStep	Required	URI	urn:epcglobal:cbv:bizstep:commissioning	CBV standard definition
disposition	Required	URI	urn:epcglobal:cbv:disp:active	CBV standard definition: the *Disposition* value "active" is always used with the *Business Step* "commissioning."
readPoint	Optional	URI	EPC Pure Identity URI for the GLN of the location at which the event took place (see Section 14.2).	EPCIS standard definition
bizLocation	Required	URI	EPC Pure Identity URI for the GLN of the location where the objects are presumed to be following the event (see Section 14.2).	EPCIS standard definition
bizTransactionList	Omitted	List of biz transactions (each		Omitted in Commissioning events as there are no relevant

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❖ **Extensions used in Commissioning Events:**

In addition to the EPCIS standard fields shown above, the following extensions are also included in a Commissioning event. (See Section 15 for general notes about extensions.)

Element	Usage	Type	Value
eventID	Optional	String	A universally unique identifier (UUID) as defined by IETF RFC 4122 that uniquely identifies this event, using the URN syntax also defined in RFC 4122. Currently this event ID is added here for the purposes of pilots to test the use and value of an ID for identifying and referencing EPCIS events (void, replace, etc.). *It is possible that this attribute will be adopted into the EPCIS standard and promoted to the standard set of attributes. At that time, this attribute will be removed from the extension as part of a future version of this guideline.*
additionalTradeItemIdentification	Conditional	AdditionalTradeIdentificationType (see below)	The product code associated with all of the EPCs in the epcList of the ObjectEvent.
tradeItemMasterData	Conditional	Complex Type tradeItemMasterData (see below)	Used for trading partners who do not employ a master data management strategy
lotNumber	Conditional (see notes below)	String	The lot or batch number for all of the EPCs in the epcList of the ObjectEvent
itemExpirationDate	Conditional (see notes below)	Date	The expiration date for all of the EPCs in the epcList of the ObjectEvent, formatted as an xsd:date. *

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❖ **Commissioning Event Example:**

```
<epcis:EPCISDocument
    xmlns:gs1ushc="http://epcis.gs1us.org/hc/ns"
    xmlns:epcis="urn:epcglobal:epcis:xsd:1"
    schemaVersion="1.0"
    creationDate="2012-03-25T17:10:16Z">
  <EPCISBody>
    <EventList>
      <ObjectEvent>
        <eventTime>2012-03-25T17:10:16Z</eventTime>
        <eventTimeZoneOffset>-05:00</eventTimeZoneOffset>
        <epcList>
          <epc>urn:epc:id:sgtin:030001.0012345.10000000001</epc>
          <epc>urn:epc:id:sgtin:030001.0012345.10000000002</epc>
          <epc>urn:epc:id:sgtin:030001.0012345.10000000003</epc>
          <epc>urn:epc:id:sgtin:030001.1012345.22222222222</epc>
        </epcList>
        <action>ADD</action>
        <bizStep>urn:epcglobal:cbv:bizstep:commissioning</bizStep>
        <disposition>urn:epcglobal:cbv:disp:active</disposition>
        <readPoint>
          <id>urn:epc:id:sgln:030001.111111.0</id>
        </readPoint>
        <bizLocation>
          <id>urn:epc:id:sgln:030001.111111.0</id>
        </bizLocation>
        <gs1ushc:eventID>urn:uuid:f81d4fae-7dec-11d0-a765-00a0c91e6bf6</gs1ushc:eventID>

        <gs1ushc:additionalTradeItemIdentification>

<gs1ushc:additionalTradeItemIdentificationValue>0001012345</gs1ushc:additionalTradeItemIdentificationValue>

<gs1ushc:additionalTradeItemIdentificationType>NDC442</gs1ushc:additionalTradeItemIdentificationType>
        </gs1ushc:additionalTradeItemIdentification>
        <gs1ushc:tradeItemMasterData>
          <gs1ushc:drugName>Epcistra</gs1ushc:drugName>
          <gs1ushc:manufacturer>GS1 Pharma LLC</gs1ushc:manufacturer>
          <gs1ushc:dosageForm>PILL</gs1ushc:dosageForm>
          <gs1ushc:strength>100mg</gs1ushc:strength>
          <gs1ushc:containerSize>500</gs1ushc:containerSize>
        </gs1ushc:tradeItemMasterData>
        <gs1ushc:lotNumber>A123</gs1ushc:lotNumber>
        <gs1ushc:itemExpirationDate>2015-03-15</gs1ushc:itemExpirationDate>
      </ObjectEvent>
    </EventList>
  </EPCISBody>
</epcis:EPCISDocument>
```

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Figure 17: Model for EPCIS Choreography Diagrams

19.1.1. Ship a full case through the supply chain

The following examples depict a Manufacturer shipping a pallet of cases to a Wholesaler who then breaks the pallet down to its cases and ships a full case to the Dispenser warehouse.

In the Figure 19 scenario, each trading partner captures the correct EPCIS events; however, they only share the *Shipping* event with each other. (If necessary, each trading partner could collect the remaining events from their trading partners to assemble the full history of events for a particular trade item.)

BASIC FORWARD LOGISTICS
A HOMOGENEOUS CASE MOVES FROM MANUFACTURER TO WHOLESALER TO DISPENSER – SHARING ONLY SHIPPING INFORMATION (1-UP/1-DOWN)

Manufacturer	Wholesaler	Dispenser
$C^M_{[TI]}$	$R^W_{[PA]}$	$R^D_{[CA]}$
$C^M_{[CA]}$	$U^W_{[CA/PA]}$	$U^D_{[TI/CA]}$
$C^M_{[PA]}$	$R^W_{[CA]}$	$E^D_{[TI]}$
$P^M_{[TI/CA]}$	$S^W_{[CA]}$	
$P^M_{[CA/PA]}$		
$S^M_{[PA]}$		

$S^M_{[PA]}$ (Manufacturer → Wholesaler)
$S^W_{[CA]}$ (Wholesaler → Dispenser)

Figure 19: Ship full case through supply chain -- sharing *Shipping* events only

WHAT'S NEXT?

SECURE SUPPLY CHAIN TASK FORCE
IMPLEMENTATION GUIDE - TIMELINE

- Release 2.0:
  - Exception Processing
  - Forward Logistics (drop shipments, repackaging, kitting)?
  - Reverse Logistics (Returns, Recalls, Withdrawals, Refusals)?
  - Other Scenarios (partial shipment, partial receipt, etc.)

- Security:
  - Maintaining the integrity of the ~~data~~ information

- Checking Service?
  - Determine if a chain of custody/ownership is available

- Architecture:
  - Centralized, Decentralized, Semi-Centralized

21. List of Exceptions

To date, the GS1 Healthcare US Secure Supply Chain Task Force has identified the following list of exceptions that could occur. As these exceptions and their resolutions are documented, it may be that some have the same root cause and will be consolidated. Likewise, as pilots and implementations continue to inform the content of this guideline, other exceptions may be uncovered and documented in this section in future releases.

Exception List:

1: Overage

2: Shortage

3: Pedigree Serial Number discrepancy

4: Pedigree Lot Number discrepancy

5: Pedigree Serial Number and Lot Number incorrect

6: Product inference problem

7: Quantity inference problem

8: Physical inventory overage

9: Physical inventory overage (concealed)

ENSURING BARCODE QUALITY
CONFORMANCE TEST CARDS & DECODE AND ANALYSIS REPORT

2015 READINESS WORKSHOPS
SCHEDULE

Webinar Dates	Workshop Date
March 20	April 17
April 3	
May 8	May 22
June 6	June 19
August 21	September 18
September 4	
September 26	October 16
TBD	November 6

http://www.gs1us.org/about-gs1-us/events/2015-readiness-workshops

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IMPLEMENTATION GUIDELINE

Applying GS1 Standards to
U.S. Pharmaceutical Supply Chain Business Processes
TO SUPPORT PEDIGREE AND TRACK & TRACE

Release 1.0 (February, 2013)

THE GLOBAL LANGUAGE
OF BUSINESS

Future Versions

This document is a preliminary version of the implementation guideline. It is anticipated that it will undergo changes as the industry engages in pilots and implementations of product serialization, track and trace, and pedigree applications. Comments to this document should be sent to GS1 Healthcare US via rceleste@gs1us.org. The document may be updated, replaced or made obsolete by other documents at any time. Please check the GS1 Healthcare US website frequently for the latest version of the document. http://www.gs1us.org/healthcare

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Contents

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GS1 is a neutral, not-for-profit organization dedicated to the design and implementation of global standards and solutions to improve the efficiency and visibility in supply chains. GS1 is driven by more than a million companies, who execute more than six billion transactions a day with the GS1 System of Standards. GS1 is truly global, with local Member Organizations in 111 countries, with the Global Office in Brussels, Belgium.

About GS1 US®

GS1 US is the Member Organization of GS1 that serves companies in the United States. As such, it is the national implementation organization of the GS1 System dedicated to the adoption and implementation of standards-based, global supply chain solutions in the United States. GS1 US currently serves over 200,000 U.S. member companies -- 16,000 of which are in healthcare.

About GS1 Healthcare

GS1 Healthcare is a global, voluntary healthcare user group developing global standards for the healthcare supply chain and advancing global harmonization. GS1 Healthcare consists of participants from all stakeholders of the healthcare supply chain: manufacturers, wholesalers & distributors, as well as hospitals and pharmacy retailers. GS1 Healthcare also maintains close contacts with regulatory agencies and trade organizations worldwide. GS1 Healthcare drives the development of GS1 Standards and solutions to meet the needs of the global healthcare industry, and promotes the effective utilization and implementation of global standards in the healthcare industry through local support initiatives like GS1 Healthcare US in the United States.

About GS1 Healthcare US®

GS1 Healthcare US is an industry group that focuses on driving the adoption and implementation of GS1 Standards in the healthcare industry in the United States to improve patient safety and supply chain efficiency. GS1 Healthcare US brings together members from all segments of the healthcare industry to address the supply chain issues that most impact healthcare in the United States. Facilitated by GS1 US, GS1 Healthcare US is one of sixty-six local GS1 Healthcare user groups around the world that supports the adoption and implementation of global standards developed by GS1.

Part 1: Preface

1. Introduction

California state drug pedigree requirements become mandatory in 2015, marking the beginning of product serialization and visibility in the healthcare supply chain. In response, members of the United States pharmaceutical industry have been preparing their systems and business processes to meet those requirements. During this journey, the healthcare industry has rallied around the use of Electronic Product Code™ Information Services (EPCIS) for pedigree and track and trace. The EPCIS is a GS1 Standard that enables supply chain partners to capture event information about supply chain events (e.g., shipped; received; etc.), and to share that information with their trading partners securely and in near real-time.

The EPCIS is a flexible standard that can be leveraged for a wide variety of business needs. There are numerous options for how the standards can be implemented in order to accommodate different applications and environments. Nonetheless, there still needs to be a certain level of consistency in terms of how the standards are implemented by individual trading partners in order to support collaborative supply chain solutions like pedigree and track and trace.

Therefore, members of the U.S. pharmaceutical industry joined forces to determine how the standards can best be applied to support pedigree and track and trace. Over fifty organizations from across the U.S. pharmaceutical supply chain participated. Leading manufacturers, wholesalers, retail pharmacies, healthcare providers, government agencies and industry associations all worked together to analyze business processes and post-2015 business requirements, consider the various options, and decide how the standards should be applied.

To support testing and analysis, they created a computerized model of the U.S. pharmaceutical supply chain that simulates forward logistics and reverse logistics processes using GS1 Standards for product serialization and visibility.   All of their decisions about how the standards might be applied are embedded in that model, which is known as the Industry Reference Model for the U.S. Pharmaceutical Industry. The reference model provides an example of an implementation, reflecting the current wisdom in industry for how the standards can best be applied to support the needs of the U.S. pharmaceutical supply chain.

This document records all of the decisions points for how the standards are applied. By so doing, this document serves an implementation guideline that shows industry members how to apply the standards to their own business processes to support pedigree and track and trace.

2. Document Information

This implementation guideline was prepared by GS1 US and the Secure Supply Chain Task Force of the Traceability Adoption Workgroup to assist the U.S. pharmaceutical industry in implementing GS1 Standards to support pedigree and track and trace. It is based on the *GS1 General Specification*, the *EPC Tag Data Standard*, the *Tag Data Translation Standard,* and the *EPCIS Standard*. It was developed using information obtained from all members of the U.S. pharmaceutical supply chain from manufacturers to providers.

2.1.   Purpose

This document identifies the GS1 Standards used and provides details about how they can be applied toward the purposes of product serialization, track and trace and pedigree. Included are all of the EPCIS *Business Step* and *Product Disposition* combinations used for each supply chain event. By so doing, this document serves an implementation guideline that directs industry members about how to apply the standards to their own business processes to support product serialization, pedigree and track and trace within the U.S. pharmaceutical supply chain.

2.2.   Content Condition

This document is a working draft that reflects the <u>current</u> level of thought within industry.   As such, it will undergo changes as the Traceability Adoption Workgroup deems necessary to reflect feedback from industry pilots, architecture work being conducted by GS1, and other industry efforts which advance the level of thought. The content may be of assistance as a resource for understanding current thinking or as an aid for pilot preparation. The reader should be aware that changes will be made frequently and should not expect any particular section of content to remain unchanged in the first release.

2.3.   Version Updates

Version	Date	Update Notes	Reviewed by Team	Approved for Draft by Team
Release 1.0	02/01/2012	Initial release.		

Table A: Document Version History

2.4.   Scope

This guideline presents the current wisdom in industry for how GS1 Standards can best be applied to U.S. pharmaceutical supply chain business processes to support pedigree and track and trace. It does not provide any guidance or advice regarding regulatory compliance.

- The content of a valid ePedigree is specified in pedigree regulations, and companies should consult those regulations for information, guidance and/or advice regarding regulatory compliance.

- The Drug Pedigree Messaging Standard (DPMS) defines an XML data format designed specifically to satisfy pedigree requirements.

- The DPMS complies with all known U.S. pedigree laws, and is currently the only pedigree format approved by regulators.

- The use of EPCIS events along with specific product and location master data provides a means for trading partners to accumulate the information that would be found in the *Drug Pedigree Messaging Standard (DPMS)*.

2.5.   Normative References

This application guideline is based on the *GS1 General Specification*, the EPC Tag Data Standard, the Tag Data Translation Standard, and the EPCIS Standard. The specific standards referenced in this guideline are listed below, and the relevant provisions of these standards/specifications are to be considered provisions of this guideline:

- *GS1 General Specification* – Available in the Knowledge Center through the GS1 website at *www.gs1us.org/solutionscenter*

- EPC Tag Data Standard – Available in the Knowledge Center through the GS1 website at *http://www.gs1.org/gsmp/kc/epcglobal*

- Tag Data Translation Standard – Available in the Knowledge Center through the GS1 website at *http://www.gs1.org/gsmp/kc/epcglobal*

- EPCIS Standard – Available in the Knowledge Center through the GS1 website at *http://www.gs1.org/gsmp/kc/epcglobal*

- Core Business Vocabulary Standard – Available in the Knowledge Center through the GS1 website at *http://www.gs1.org/gsmp/kc/epcglobal*

- GTIN Allocation Rules

- GTIN Allocation Rules for Healthcare

- GLN Allocation Rules

2.6. Non-normative References

Material in this application guideline is based on a number of non-normative guidelines and references available from GS1 and GS1 US. The specific guidelines and documents referenced in this guideline are listed below, and the relevant provisions of these standards/specifications are to be considered provisions of this guideline:

- *GS1 RFID Bar Code Interoperability Guideline -* Available in the Knowledge Center through the GS1 website at http://www.gs1.org/gsmp/kc/barcodes

- *Healthcare Provider GTIN Tool Kit* – Available on the GS1 US website at http://www.gs1us.org/hctoolkit

- *Healthcare Supplier GTIN Tool Kit* – Available on the GS1 US website at http://www.gs1us.org/hctoolkit

- *Healthcare Provider GLN Tool Kit* – Available on the GS1 US website at http://www.gs1us.org/hctoolkit

- *Healthcare Supplier GLN Tool Kit* – Available on the GS1 US website at http://www.gs1us.org/hctoolkit

- *Healthcare Provider GDSN Tool Kit* – Available on the GS1 US website at http://www.gs1us.org/hctoolkit

- *Healthcare Supplier GDSN Tool Kit* – Available on the GS1 US website at http://www.gs1us.org/hctoolkit

- *The Practice of Inference in the U.S. Pharmaceutical Supply Chain -* Available on the GS1 US website at www.gs1us.org/hctools

2.7. Additional Considerations & Resources

- GS1 DataMatrix requires camera-based scanners. Traditional laser barcode scanners cannot read the GS1 DataMatrix. As a result, it is important for supply chain partners to communicate prior to implementing GS1 DataMatrix to ensure that the appropriate scanners are in place.

- Prior to purchasing barcode scanning equipment, it is recommended that you consult the *Simplified Guide for U.S. Healthcare Barcode Scanner Acquisition Criteria* (see the Resources page in the Appendix for the link). This document was prepared by GS1 US to assist members of the U.S. healthcare supply chain in evaluating the various barcode scanning equipment options on the market, and selecting the equipment that best fits their needs.

- There are many reasons why a barcode may not scan. Many times it is not the barcode, but the scanner itself. For example, the lens could be dirty or the batteries discharged. GS1 US prepared another document entitled *Procedure for Responding to Troublesome Barcodes* (see the Resources page in the Appendix for the link) to help resolve barcode scanning issues. This document offers a simplified process to rectify barcode scanning issues based on the experiences of healthcare users. It is recommended that you download this document as a reference to help you respond if a barcode does not scan.

3. Overview of the GS1 Standards Used

This chapter provides a brief definition of each GS1 Standard used in the industry reference model. (Refer to the Appendix of this document for more information about GS1 Standards that support pedigree and track and trace.)

3.1.   Global Location Number (GLN)

The Global Location Number (GLN) is the globally unique GS1 Identification Number for locations and supply chain partners. The GLN can be used to identify a *functional entity* (like a hospital pharmacy or accounting department), a *physical entity* (like a warehouse or hospital wing or even a nursing station), or a *legal entity* (like a health system corporation). The attributes defined for each GLN [e.g., name, address, location type (e.g., ship to, bill to, deliver to, etc.)] help users to ensure that each GLN is specific to one unique location within the world.

3.2.   Global Trade Item Number® (GTIN®)

The Global Trade Item Number (GTIN) is the globally unique GS1 Identification Number used to identify "trade items" (i.e., products and services that may be priced, ordered or invoiced at any point in the supply chain). GTINs are assigned by the brand owner of the product, and are used to identify products as they move through the global supply chain to the hospital or ultimate end user. The GTIN uniquely identifies a product at each packaging level (e.g., a bottle of 100 aspirin tablets; a case of 200 bottles of aspirin tablets, etc.).

3.3.   Serial Shipping Container Code (SSCC)

The Serial Shipping Container Code (SSCC) is the globally unique GS1 Identification Number used to identify individual logistic units (i.e., an item of any composition established for transport and/or storage which needs to be tracked individually and managed through the supply chain). The SSCC is assigned for the lifetime of the transport item and is a mandatory element on the GS1 Logistic Label. SSCCs serve as "license plates" from the carton level to the trailer load level to facilitate simple tracking of goods and reliable look up of complex load detail.

3.4.   GS1 Data Carriers

GS1 Data Carriers provide *machine-readable representations* of GS1 Identification Numbers that facilitate automatic identification and data capture. In order to accommodate a variety of environments and applications, the GS1 System supports eight data carriers: six barcode symbologies (i.e., GS1 Barcodes) and two RFID tags [i.e., GS1 Electronic Product Code / Radio Frequency Identification Tags (EPC/RFID Tags)].

3.5.   GS1 Application Identifiers

GS1 Application Identifiers (AIs) are a finite set of specialized identifiers encoded within barcodes to indicate the type of data represented in the various barcode segments. Each AI is a two, three, or four digit numeric code. (When rendered in human-readable form, the AI is usually shown in parentheses. However, the parentheses are not part of the barcode's encoded data.) Each data element in a barcode is preceded by its AI. For example, the AI for GTIN is 01. Thus, when "01" appears in the encoded content of a barcode, it means the next 14 digits comprise a GTIN. There are approximately 100 AIs. There is an AI for each GS1 Identification Number. In addition, there are AIs for various types of secondary information to enable supply

chain partners to communicate item-specific information wherever the barcode is scanned (e.g., expiration date; lot number; batch number). GS1 AI's commonly used in healthcare include AI (10) for Lot/Batch Number, AI (17) for Expiration Date, and AI (21) for Serial Number.

3.6. EPC Information Service (EPCIS)

The EPC Information Service (EPCIS) standard defines a data-sharing interface that enables supply chain partners to capture and communicate data about the movement and status of objects in the supply chain. The EPCIS specification provides technical standards, as well as a standardized set of service operations and associated data elements. In addition, the EPCIS standard also incorporates data standards for how to populate EPCIS data elements. (See Core Business Vocabulary below.)

3.7. Core Business Vocabulary (CBV)

The Core Business Vocabulary (CBV) provides data standards for populating EPCIS data elements. The CBV provides lists of acceptable values for how to express what business process was operating on an object and the status of the object upon exiting the process. It includes syntaxes, vocabularies, and element values (with definitions).

3.8. GLN Registry

The GLN Registry is the single source of truth for healthcare location information, offering a comprehensive list of healthcare and healthcare-related facilities in the United States with corresponding Global Location Numbers (GLNs). The GLN is the globally recognized identification number used in the GS1 System to uniquely identify legal entities, trading partners, and locations in electronic commerce transactions. The GLN Registry enables subscribers to access up-to-date, reliable location information, validated by the U.S. Postal Service, for manufacturers, distributors, retailers, hospitals, clinics, as well as retail and mail-order pharmacies in order to improve the accuracy of their supply chain activities.

3.9. Global Data Synchronization Network™ (GDSN®)

The Global Data Synchronization Network (GDSN) provides an efficient and effective approach to (1) storing GS1 Identifiers with their associated attributes, (2) checking to make sure that the identifiers and attributes are properly defined and formatted, and (3) sharing that information with supply chain partners. The GDSN is a network of interoperable data pools connected by the GS1 Global Registry®. The GDSN-certified Data Pools store and manage supply chain information for their users, and the GS1 Global Registry connects those data pools together. The GDSN offers a continuous, automated approach to data management that ensures that supply chain information is identical among trading partners, increasing data accuracy and driving costs out of the supply chain.

4. Background Concepts

4.1.   Relationship between NDC – GTIN – SGTIN

The FDA National Drug Code (NDC) is a U.S. regulatory identifier used to identify pharmaceutical products for regulatory purposes. The GTIN is a supply chain identifier used to identify *products* for supply chain purposes. The SGTIN is a supply chain identifier used to identify *individual instances of a product* for supply chain purposes. There is a cohesive, hierarchical relationship between these identifiers. As illustrated in Figure 1, NDCs can be embedded into GTINs so that identification of pharmaceutical products for supply chain purposes is consistent with identification of pharmaceutical products for regulatory purposes. GTINs can then be supplemented with serial numbers to identify individual instances of the pharmaceutical product.

Figure 1:   Relationship of the NDC, GTIN and SGTIN

4.2.   NDC Labeler Code & GS1 Company Prefix

The NDC is a 10-digit identifier comprising two segments: a *Labeler Code* assigned by the FDA and a *Product/Package Code* assigned by the manufacturer. The *Labeler Code* is a variable length identifier assigned by the FDA (and encoded into NDCs) to identify a company that manufactures a drug (including repackers or relabelers) or distributes a drug (under its own name).

GS1 US has reserved a placeholder in the GS1 Company Prefix numbering system that enables the NDC *Labeler Code* to be integrated into the GS1 Company Prefix for pharmaceutical companies. The placeholder (named the "GS1 Prefix") is **03**, and the GS1 Company Prefix for a pharmaceutical company is simply its *Labeler Code* with "03" appended in front. For example:

GS1 Prefix	**03**
FDA-assigned *Labeler Code*	**61414**
GS1 Company Prefix	**0361414**

ⓘ *In order to use a Labeler Code as a GS1 Company Prefix, manufacturers must first contact GS1 US to have a GS1 Company Prefix that embeds their Labeler Code assigned to the company.*

Pharmaceutical companies may have more than one GS1 Company Prefix (e.g., one GS1 Company Prefix that integrates their NDC *Labeler Code*, and other GS1 Company Prefixes that do not). Those companies will need to use the GS1 Company Prefix that integrates their *Labeler Code* when assigning GTINs that embed NDCs (discussed below). However, they may use whichever GS1 Company Prefix they prefer to generate SSCCs and GLNs.

4.3.   Integrating NDCs into GTINs

As noted above, NDCs can be integrated into GTINs. Figure 2 illustrates how the two NDC segments (i.e., *Labeler Code* and *Product/Package Code*) are integrated into the segments of a GTIN-14. The NDC *Labeler Code* is integrated into a GS1 Company Prefix (as described above). The NDC *Product/Package Code* is used to populate the Item Reference segment of the GTIN.

0 0 3 6 1 4 1 4 5 6 7 8

Position 1 — Indicator Digit

Position 2 – Position 13

GS1 Company Prefix   +   Item Reference

03 + FDA Labeler Code   NDC Product/Package

Position 14 — Check Digit

Figure 2: Segments of a GTIN-14 that embeds an NDC (based on the hypothetical GTIN "00361414567894")

4.4.   Assigning vs. Storing vs. Encoding GTINs

GTINs can be assigned as 8 digits, 12 digits, 13 digits, or 14 digits in length. Within the U.S. pharmaceutical supply chain, the 12-digit GTIN ("GTIN-12") and the 14-digit GTIN ("GTIN-14") are predominantly used. Regardless of how they are assigned, it is important to understand that GTINs are always encoded in barcodes ⓘ and stored in databases in 14-digit format.

Assigning GTINs	Storing GTINs	Encoding GTINs
GTIN-12 or GTIN-14	**14-digit format**	**14-digit format** ⓘ
	(i.e. GTIN-14 or GTIN-12 in 14-digit format using leading zeros)	(i.e. GTIN-14 or GTIN-12 in 14-digit format using leading zeros)

Table B: Key to Assigning, Storing and Encoding GTINs

ⓘ *The exception is the UPC-A, which is the only barcode in which GTINs are encoded as 12 digits.*

4.5.   Marking Products with Both UPC-A and GS1 DataMatrix

As of this writing, FDA regulations require pharmaceutical products to be marked with a linear barcode that carries their NDC. Serialization requirements and pedigree regulations typically require pharmaceutical products to be marked with a barcode that carries their NDC, a serial number, and possibly other secondary information such as lot/batch or expiration date. To satisfy these requirements, many pharmaceutical manufacturers are marking products that move through a Point of Sale (POS) with both a UPC-A *(to satisfy the FDA linear barcode requirement)* and a GS1 DataMatrix *(to satisfy serialization/pedigree requirements)*. (See the note in Section 8.1.1 for more information.)   The UPC-A holds a maximum of 12 digits, but the GS1 DataMatrix requires the GTIN to be in a format that is 14 digits long. In order to ensure that the GTIN encoded in both barcodes is the same, manufacturers should follow the recommendations below for all products that will be marked with both a UPC-A and a GS1 DataMatrix:

- assign a GTIN-12 to identify the product at the lowest saleable level (i.e., the bottle or pack)

- create the UPC-A linear barcode using the GTIN-12

- pad the GTIN-12 with two leading zeros to create a "GTIN-12 in 14-digit format" ⓘ

GTIN-12	31414 199999 5
GTIN-12 in 14-digit format	0 031414 199999 5

- when storing GTIN-12s in databases, store them in the 14-digit format

- use the "GTIN-12 in 14-digit format" when encoding the GS1 DataMatrix (along with Expiration Date, Lot Number and Serial Number for serialization purposes)

ⓘ **THIS SHOULD NOT BE DONE IN THE OPPOSITE DIRECTION** *(i.e., assign a GTIN-14 and remove the first two digits in an attempt to create a GTIN-14 in a 12-digit format). A true GTIN-14 (one with digits other than "00" in the 1st and 2nd positions) cannot be converted to a 12-digit format because, among other reasons, the check digit (which is calculated using the value and position of each digit) would not match.*

A GTIN-12 remains a GTIN-12 whether it is in its original 12-digit format or represented in a 14-digit format using leading zeros. Technically speaking, the padded GTIN-12 is called a "GTIN-12 in a 14-digit format." It is not a GTIN-14. Therefore, when a product needs to be marked with a UPC-A, it should be assigned a GTIN-12 (not a GTIN-14) in order to preserve the manufacturer's ability to represent the GTIN in a 12-digit U.P.C. as well as any barcode that requires a 14-digit format.

4.6.   Case Identification

Cases can be identified using GTIN + serial number or using SSCC, depending on how the case is being used:

- **Use GTIN + serial number if the case is orderable and if your customer is expecting to identify the contents from the case barcode or EPC/RFID tag**

- **Use SSCC if the case is to be treated as a logistics unit**

4.7.   Location Identification: Data Capture vs. Data Reporting

The reference model includes a table that provides a reference between a business location (i.e., a building with an address) and internal locations (e.g., loading dock; doorway; etc.). The model captures EPCIS events at the internal location level, and produces EPCIS events for trading partners at the business location level. For example, a manufacturer may capture the location of a palletizer as cases are aggregated or packed onto a pallet. The EPCIS event that is generated for trading partners will include the location of the manufacturing site, not the palletizer itself. The manufacturer may decide to store the lower level location (palletizer) for their own purposes and report a higher level location (the production plant) for the purposes of external track and trace.

4.8.   EPCIS & the URI

EPCIS stores identifiers (e.g., GTIN + serial number; SSCC; GLN; etc.) in URI format. "URI" stands for Uniform Resource Identifier, which is used in many Internet-based software systems to refer to any resource on the network. There are two types of URIs: Uniform Resource Names (URNs) and Uniform Resource Locator (URLs). The EPCIS data format standard is a URN which takes the following form:

urn:epc:id:*scheme*:*component1*.*component2*….

Scheme names an EPC scheme, and the content and format of the remainder of the URI string (i.e., *component1*, *component2*, etc.) depends on which EPC scheme is being used. Each EPC scheme provides a namespace of identifiers that can be used to identify physical objects of a particular type. There are seven EPC schemes that correspond to GS1 keys. For example, the EPC scheme for SGTIN is provided below:

General syntax: urn:epc:id:sgtin:*CompanyPrefix*.*ItemReference*.*SerialNumber*

Example: urn:epc:id:sgtin:0614141.112345.400806

The URI scheme to be used for GTIN + serial number, SSCC and GLN are provided in the relevant sections of this manual.

4.9.   Determining the Length of GS1 Company Prefixes for URIs

When translating data from URI formats, it is necessary to indicate the length of the GS1 Company Prefix (i.e., how many digits within the GS1 Key belong to the GS1 Company Prefix). Because GS1 Company Prefixes are issued in varying lengths, you will need to obtain the length of each GS1 Company Prefix you expect to encounter in your EPCIS events.   To facilitate this, GS1 US has published a list of U.S. GS1 Company Prefixes that you can download and use (www.gs1us.org/gcplist). Alternatively, you can ask your trading partners for the length of their GS1 Company Prefixes and create your own table. (You can even make this part of your on-boarding process for vendors.)

4.10.   Inference

Inference is the process a supply chain partner uses to ensure there is enough evidence to infer the <u>serialized</u> number without physically reading ALL serialized numbers. Inference applies in instances where a collection is moved through the supply chain in an outer container (e.g., pallets; cases; totes; etc.), and less than 100% of data carriers in that collection are read by recipients. In such circumstances, inference enables the recipient of the collection to leave the outer container intact (un-opened) so as not to undermine tamper-evident security features. To gain a more complete understanding of what is contained in the entire collection, the recipient reads the serialized identifiers for the visible items, cross-checks them with the shipping documents for the collection and outer container bundle, and verifies the integrity of the outer container bundle and its security features. If all three conditions are confirmed, the rest of the items in the collection can be inferred to be present.

Inference is a mechanism that enables supply chain partners to leverage strong supply chain practices to meet the potential challenges associated with the receiving/shipping of serialized items. For more information, see the GS1 US white paper entitled *The Practice of Inference in the U.S. Pharmaceutical Supply Chain* (see References above for link).

Use of Inference in examples:

For internal levels of packaging where either barcodes are used or EPC/RFID devices are unreadable, the trading partner in possession of the object is said to have inferred the existence of internal layers of packaging that cannot be read at the time of the event and may exercise an inference SOP for that purpose.

4.11.   Use of Inference

For internal levels of packaging where either barcodes are used or RFID devices are unreadable, the trading partner in possession of the object is said to have inferred the existence of internal layers of packaging that cannot be read at the time of the event and may exercise an inference SOP for that purpose.

4.12.   Drug Pedigree Messaging Standard (DPMS)

The content of a valid ePedigree is specified in pedigree regulations. At the time of publication, the DPMS complied with all known U.S. pedigree laws. The present guideline makes use of GS1 Visibility standards including Global Data Synchronization Network (GDSN), EPCIS, Core Business Vocabulary and the Tag Data Standard to manage, share and assemble pedigree data.

The documented EPCIS events and Master Data Management architecture provides for reporting capabilities that provide all of the information that would be found in the DPMS.

Part 2: Identify

GS1 Identification Numbers globally and uniquely identify supply chain objects (e.g., products, assets, logistic units, etc.), as well as supply chain partners and physical locations. Table 3 lists the GS1 identification standards used in this guideline to support pedigree and track and trace.

Supply Chain Object or Location	Corresponding GS1 Identifier	Instance
Companies and warehouses	GLN	
Specific locations within companies & warehouses	GLN + extension	
Item	GTIN	GTIN + serial number
Kit	GTIN	GTIN + serial number
Homogeneous Case	GTIN	GTIN + serial number, SSCC
Mixed / Partial Case		SSCC
Pallet		SSCC
Tote		SSCC

Table C: GS1 Identifiers[1]

[1] There may be other layers of packaging that are not specified here.

5. Identifying Trade Units (Products, Cases and Kits): GTIN

In the GS1 System, products, cases and kits[2] are identified with the Global Trade Item Number (GTIN). GTIN is a globally unique, standards-based, identification number for trade items. When a manufacturer assigns ("allocates") a GTIN, they define a prescribed set of data about the product to which that GTIN relates. These *product description attributes* define master data that is consistent across all instances of the product (e.g., size; color; brand information; etc.). GS1 Standards specify the list of attributes that must be defined for each GTIN, as well as the permissible values. Once the GTIN is allocated and the attributes are defined, the GTIN and its associated attributes are then saved in a database (like a GDSN-certified Data Pool) and shared among supply chain partners. (The section of this guideline entitled "Master Data Management" explains how this information can be combined with EPCIS event information to obtain supply chain visibility.)

 (NOTE: *GS1 US provides an online tool, known as Data Driver®, to support users in allocating GTINs and defining the associated attributes.* Visit http://www.gs1us.org/resources/tools/data-driver *for more information.*)

5.1. Assigning GTINs

GTINs can be assigned as 8 digits, 12 digits, 13 digits, <u>or</u> 14 digits in length (known as GTIN-8, GTIN-12, GTIN-13 and GTIN-14, respectively). However, within the U.S. pharmaceutical supply chain, the GTIN-12 and the GTIN-14 are predominantly used. The choice of format is related to point of sale:

- **Assign a GTIN-12 to pharmaceuticals products that will be scanned at point of sale** *(see Section 4.5 for more information)*

- **Assign a GTIN-14 to pharmaceuticals that will <u>not</u> be scanned at point of sale**

5.1.1. Creating a GTIN-12

Each GTIN-12 is a numerical string comprising three distinct segments. The three segments within a GTIN-12 are:

- **U.P.C. Company Prefix:** A specific representation of a GS1 Company Prefix that serves as the foundation for generating GTIN-12 identifiers. U.P.C. Company Prefixes vary in length depending on the company/organization's needs.   In a GTIN-12 that embeds an NDC, the U.P.C. Company Prefix segment is populated with the NDC Labeler Code with a "3" appended in front.

- **Item Reference:** A number assigned by the holder of the U.P.C. Company Prefix to uniquely identify a trade item. The *Item Reference* varies in length as a function of the U.P.C. Company Prefix length. (Refer to the *GS1 General Specifications* and the *GTIN Allocation Rules for the Healthcare Sector* for additional information.) In a GTIN-12 that embeds an NDC, the *Item Reference* segment is populated with the NDC Product/Package Code*.

- **Check Digit:** A one-digit number calculated from the first 11 digits of the GTIN-12 used to ensure data integrity. GS1 US provides a check digit calculator to automatically calculate check digits for you. The check digit calculator can be found at http://www.gs1us.org/resources/tools-and-services/check-digit-calculator .

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[2] Consult the FDA UDI (Unique Device Identification) Rule for Kits that include a medical device.

Although the length of the U.P.C. Company Prefix and the length of the *Item Reference* vary, they will always be a combined total of 11 digits in a GTIN-12. The addition of the *Check Digit* completes the 12 digits of the GTIN-12. Figure 3 provides a color-coded example of a hypothetical GTIN-12 that embeds an NDC, and a key explaining how each digit is populated.   (Figure 3 uses hypothetical GTIN **312345678906**.)

Example of a GTIN-12 with an NDC embedded

GTIN-12	3	1	2	3	4	5	6	7	8	9	0	6
Digit/Position	1	2	3	4	5	6	7	8	9	10	11	12

How to Populate Each Digit *(color-coded to coordinate with the GTIN-12 shown above)*

Position 1	GS1 Prefix "3"
Position 2 through 11	NDC *Labeler Code* as assigned by FDA plus NDC *Product/Package Code* created by the manufacturer (Although the length of the *Labeler Code* and the *Product/Package Code* vary, they will always be a combined total of 10 digits.)
Position 12	Check Digit

Figure 3: Populating the 12 digits of a GTIN-12 with an NDC embedded

5.1.2. Creating a GTIN-14

Each GTIN-14 is a numerical string comprising four distinct segments. The four segments in a GTIN-14 are:

- **GS1 Indicator Digit:** The indicator digit identifies packaging level. The field consists of a numeric value from 1 to 8. (The number "0" is used in this position as a fill character when a GTIN-12 or GTIN-13 is written in 14-digit format.)

  Packaging specialists must review the Indicators used on all other packaging levels prior to incorporating a new packaging level for a product. This ensures that there is a unique GTIN on every packaging level, which is imperative to preserve the uniqueness of each GTIN.

- **GS1 Company Prefix:** A globally unique number assigned to a company/organization by GS1 US to serve as the foundation for generating GS1 identifiers (e.g., GTINs). GS1 Company Prefixes are assigned in varying lengths depending on the company/organization's needs.   In a GTIN-14 that embeds an NDC, the GS1 Company Prefix segment is populated with the NDC Labeler Code with a "03" appended in front.

- **Item Reference:** A number assigned by the holder of the GS1 Company Prefix to uniquely identify a trade item. The *Item Reference* varies in length as a function of the GS1 Company Prefix length. (Refer to the *GS1 General Specifications* and the *GTIN Allocation Rules for the Healthcare Sector* for additional information.) In a GTIN-14 that embeds an NDC, the *Item Reference* segment is populated with the NDC Product/Package Code.

- **Check Digit:** A one-digit number calculated from the first 13 digits of the GTIN used to ensure data integrity. GS1 US provides a check digit calculator to automatically calculate check digits for you.   The check digit calculator can be found at http://www.gs1us.org/resources/tools-and-services/check-digit-calculator .

Although the length of the GS1 Company Prefix and the length of the Item Reference vary, they will always be a combined total of 12 digits in a GTIN-14. The *Indicator Digit* and the *Check Digit* comprise the remaining 2 digits of the GTIN-14.   Figure 4 provides a color-coded example of a hypothetical GTIN-14 that embeds an NDC, and a key explaining how each digit is populated.   (Figure 4 uses hypothetical GTIN **00361414567894**.)

Example of a GTIN-14 with an NDC embedded

GTIN	0	0	3	6	1	4	1	4	5	6	7	8	9	4
Digit/Position	1	2	3	4	5	6	7	8	9	10	11	12	13	14

How to Populate Each Digit *(color-coded to coordinate with the GTIN-14 shown above)*

Position 1	Indicator Digit (numeric value from 0 to 8)
Position 2 and 3	GS1 Prefix "03"
Positions 4 through 13	NDC *Labeler Code* as assigned by FDA plus NDC *Product/Package Code* created by the manufacturer (Although the length of the *Labeler Code* and the *Product/Package Code* vary, they will always be a combined total of 10 digits.)
Position 14	Check Digit

Figure 4: Populating the 14 digits of a GTIN-14 with an NDC embedded

5.2.   Assigning/Allocating Serial Numbers

The combination of a GTIN plus a unique serial number is used to identify a specific instance of a trade item. For example, if hypothetical GTIN 00361414567894 is assigned to identify a 100-count bottle of XYZ tablets, then the combination of GTIN 00361414567894 plus a serial number would identify a *specific* 100-count bottle of XYZ tablets. All bottles of XYZ tablets would have the same GTIN, but each bottle would be assigned a unique serial number.

The *GS1 General Specification*s define a serial number for use with a GTIN as an alphanumeric string whose length is variable between one and 20 characters *(the specific characters allowed are defined in the GS1 General Specifications)*. Therefore, databases and messages that need to contain a GTIN plus serial number should be designed to accommodate any serial number consisting of 1-20 characters. "Zero" characters in serial numbers are treated as any other alphanumeric character such that serial numbers 7, 07, and 007 are all *different* serial numbers according to the standard. Databases should treat the serial number as a text field so that leading zeros are not inadvertently stripped off.

In GS1 barcodes, serial numbers are represented using AI **(**21**)**. Any serial number consisting of 1-20 characters may be used in a GS1 barcode per the standard. Although barcodes can accommodate any 1-20 character serial number, the size of the barcode may vary depending on how many characters are used. However, many production systems prefer a consistent barcode size in order to conform to package artwork

constraints and to simplify the quality assurance process. For this reason, manufacturers often adopt a consistent serial number length rather than allow their serial numbers to vary between 1 and 20 characters.

When using EPC/RFID tags, however, certain limitations apply. As with barcodes, EPC/RFID tags having at least 198 bits of EPC memory capacity can accommodate any 1-20 character serial number. However, EPC/RFID tags having 96-197 bits of EPC memory capacity use a 96-bit encoding format (called SGTIN-96) that places limitations on the serial numbers that can be encoded. When using the SGTIN-96 encoding, the serial number must be numeric only (that is, the only characters permitted are the digits '0' through '9'), must not have any leading zeros, and must have a numeric value that is less than or equal to 274877906943.

The following Best Practices have been defined to accommodate all of the considerations described above:

- Business applications, messages, and databases should be designed to accept data from any data carrier. Specifically, this means that applications and databases should be designed to accept the full range of data values defined by GS1 Standards, including a full 14-digit GTIN and a serial number between one and 20 alphanumeric characters. The restrictions on data values that certain data carriers impose (e.g., 96-bit EPC/RFID tags) should <u>not</u> be carried through to this level.

- Applications must not add or remove leading zeros to serial numbers.

- While the standards support serial numbers beginning with "0", applications that assign serial numbers for use with GTIN should avoid serial numbers that begin with a "0" character in order to avoid errors associated with incorrect implementations.

- If 96-bit EPC/RFID tags are to be used, serial numbers must fit within the encoding constraints of the 96-bit SGTIN format as defined by the GS1 EPC Tag Data standard (described above).

- In order to support both barcodes and 96-bit EPC/RFID tags, and to achieve a consistent barcode size, a good policy would be to assign either 11-digit numeric serial numbers within the range 10000000000 – 99999999999, <u>or</u> 12-digit numeric serial numbers within the range 100000000000 – 274877906943.

- The GTIN and serial number identifies a unique instance of a product. Therefore, reuse of serial numbers for a given GTIN is not a best practice at this time. The subject of reuse has been submitted to GS1 for review.

5.3. Data Formats for Databases

5.3.1. GTIN Fields

Although the U.S. pharmaceutical supply chain uses both GTIN-14 and GTIN-12, EPCIS requires GTINs to be in a 14-digit format. Therefore, a GTIN should always be represented in software applications as 14 digits by adding leading zeros as necessary to make 14 digits. In order to preserve any leading zeros that may be present, the GTIN field should be represented in a database as a <u>text</u> field (not numeric). This is especially important for manufacturers who currently have many GTIN-12s in their systems due to the Barcode Rule.

5.3.2. Serial Number Fields

As described above, the industry best practice is for manufacturers to <u>assign</u> all numeric serial numbers of only 11-12 digits in length in order to ensure compatibility of serial numbers across bar codes and 96-bit EPD/EPC/RFID tags. Regardless, serial numbers should always be <u>stored</u> in a text field (not numeric) that is

capable of handling from one to 20 characters. Leading zeros should *never* be added or removed from serial numbers.

5.4.   Data Format for EPCIS: URI Format

Within the EPCIS, GTIN + serial number must be stored in EPC URI format. The EPC URI format for a GTIN + serial number is the Serialized Global Trade Item Number EPC (SGTIN EPC).

ⓘ *The SGTIN EPC is based on a 14-digit GTIN. Therefore, GTIN-12s will first need to be converted to a 14-digit number by adding two leading zeros. (An example of the conversion is provided below.)*

General syntax:

urn:epc:id:sgtin:*CompanyPrefix.ItemReference.SerialNumber*

Example:

urn:epc:id:sgtin:0614141.112345.400806

Grammar:

SGTIN-URI ::= "urn:epc:id:sgtin:" SGTINURIBody

SGTINURIBody ::= 2*(PaddedNumericComponent ".")GS3A3Component

The number of characters in the two PaddedNumericComponent fields must total 13 (not including any of the dot characters). The Serial Number field of the SGTIN-URI is expressed as a GS3A3Component, which permits the representation of all characters permitted in the (AI) 21 Serial Number according to the *GS1 General Specifications*. Figure 5 depicts how the element string of a GTIN + serial number corresponds to the element string of a SGTIN EPC URI:
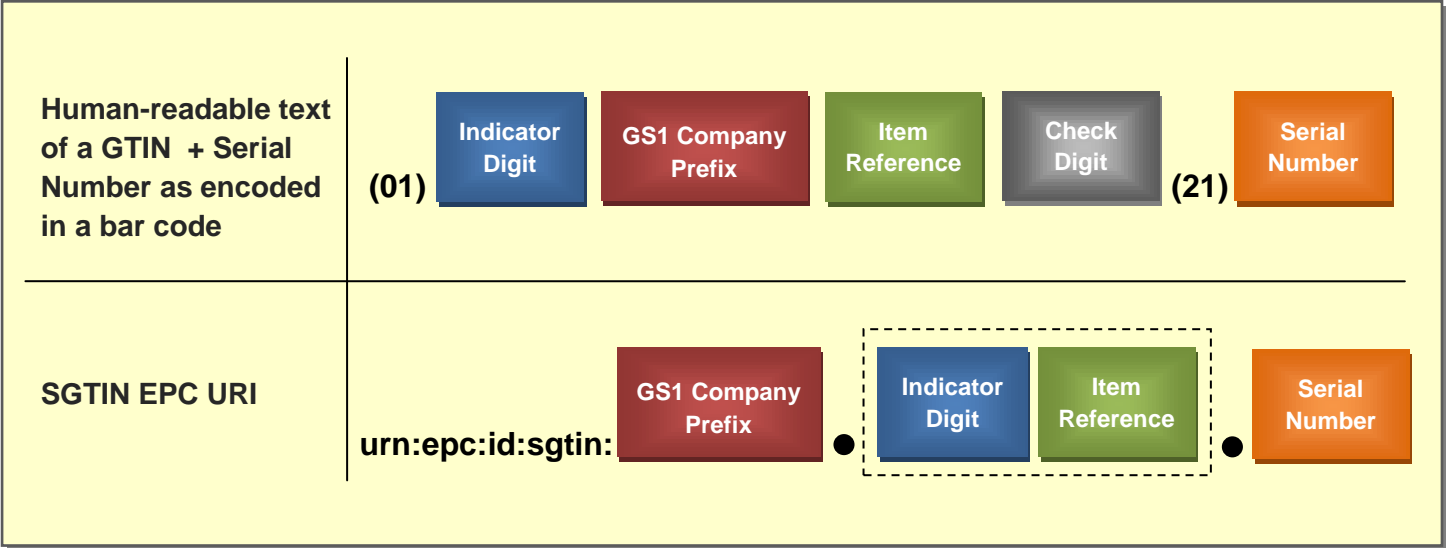
Figure 5: How the segments of a GTIN + serial number are represented in the SGTIN EPC URI format

- The GS1 Company Prefix is the same as the GS1 Company Prefix digits within the GTIN key.

- The *Item Reference* as it appears in the SGTIN EPC URI is derived from the GTIN key by concatenating the Indicator Digit of the GTIN and the Item Reference digits, and treating the result as a single numeric string.

- The *Check Digit* is not used in the EPC URI format.

- The *Serial Number* is the equivalent of AI(21).

Example – Converting a GTIN-14 + serial number into EPC URI Format:

GTIN-14	2 030001 123498 7
Serial Number	123456789012
Corresponding Barcode Human Readable Text	(01) 2 030001 123498 7 (21)123456789012
Corresponding SGTIN-EPC URI	urn:epc:id:sgtin: 030001 . 2 123498 . 123456789012

ⓘ *The spaces in the example above have been inserted for visual clarity. Those spaces are not included in either the GTIN-14 or the SGTIN EPC URI actually used within a computer system.*

Example – Converting a GTIN-12 + serial number into EPC URI Format:

To find the EPC URI corresponding to the combination of a GTIN-12 and a serial number, first convert the GTIN-12 to a 14-digit number by adding two leading zero characters. The first leading zero will serve as the Indicator Digit, and the second leading zero will serve as the first place of the U.P.C. Company Prefix as shown below:

GTIN-12	31234 567890 6
GTIN-12 in 14-digit format	0 031234 567890 6
Serial Number	123456789012
Corresponding Barcode Human Readable Text	(01) 0 031234 567890 6 (21)123456789012
Corresponding SGTIN-EPC URI	urn:epc:id:sgtin: 031234 . 0 567890 . 123456789012

ⓘ *The spaces in the example above have been inserted for visual clarity. Those spaces are not included in either the GTIN-14 or the SGTIN EPC URI actually used within a computer system.*

5.5. Data Storage Options

GTIN and serial number are assigned as separate data elements, but are saved together as an SGTIN in EPCIS. Users have several options for how to store GTIN + serial number in databases: (1) GTINs and serial numbers can be saved in their own fields; (2) saved together in the SGTIN EPC URI format (to be parsed by backend systems as needed), or (3) saved as both.

Thus, there are three options for storing GTINs and serial numbers in databases:

2 fields =	GTIN field and Serial Number field
1 field =	One field containing serialized GTIN in EPC URI format
3 fields =	GTIN field, Serial Number field, and field containing serialized GTIN in EPC URI format

Select whichever method best serves your data storage strategies. The data format for each of those fields is provided in Table 4 below:

Field	Data Format
GTIN	▪ 14 digits ▪ text field (not numeric)
Serial Number	▪ 1-20 characters ▪ text field (not numeric)
Serialized GTIN EPC URI	▪ 33-52 characters: 　▪ 17 characters for "urn:epc:id:sgtin:" 　▪ 13 characters for the GTIN (without the Check Digit) 　▪ 1-20 characters for the serial number 　▪ 2 periods (".") ▪ text field (not numeric)

Table D: Data Formats for GTIN Fields

6. Identifying Logistics Units (Cases, Pallets and Totes): SSCC

In the GS1 System, logistics units such as cases, pallets and totes are identified with the Serial Shipping Container Code (SSCC). The SSCC is an 18-digit, globally unique, standards-based, identification number for logistics units.   SSCCs serve as "license plates" from the carton level to the trailer load level to facilitate simple tracking of goods and reliable look up of complex load detail.

6.1.　　Assigning SSCCs

Suppliers are responsible for assigning (*allocating*) SSCCs to their logistics units. Each SSCC is a numerical string comprising four distinct segments. The four segments within an SSCC are:

- **Extension Digit:** The Extension Digit has no defined logic. It is available to the company to increase the capacity of the *Serial Reference.* The field consists of a numeric value from 0 to 9.

- **GS1 Company Prefix:** A globally unique number assigned to a company/organization by GS1 US to serve as the foundation for generating GS1 identifiers (e.g., GTINs; SSCCs; etc.). GS1 Company Prefixes are assigned in varying lengths depending on the company/organization's needs.

- **Serial Reference:** A number assigned by the holder of the GS1 Company Prefix to uniquely identify a logistic unit. This segment is the "serial" part of the number assigned one-by-one by the company to create a globally unique SSCC. The *Serial Reference* varies in length as a function of the GS1 Company Prefix length.

- **Check Digit:** A one-digit number calculated from the first 17 digits of the SSCC used to ensure data integrity. GS1 US provides a check digit calculator to automatically calculate check digits for you.   The check digit calculator can be found at http://www.gs1us.org/solutions_services/tools/check_digit_calculator.

Although the length of the GS1 Company Prefix and the length of the Serial Reference vary, they will always be a combined total of 16 digits in an SSCC. Figure 6 provides a color-coded example of a hypothetical SSCC, and a key explaining how each digit is populated. (Figure 6 uses hypothetical SSCC **03345678912345604**.)

Example of an SSCC

SSCC	0	0	3	3	4	5	6	7	8	9	1	2	3	4	5	6	0	4
Digit/Position	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18

How to Populate Each Digit *(color-coded to coordinate with the SSCC shown above)*

Position 1	Extension Digit (numeric value from 0 to 9)
Positions 2 through 17	GS1 Company Prefix as assigned by GS1 US <u>plus</u> Serial Reference number as assigned by the owner of the logistics unit
Position 18	Check Digit

Figure 6: Populating the 18 digits of an SSCC

6.2.   Data Format for Databases

In databases, SSCC fields should be 18 characters in length. The SSCC should be represented in a database as a <u>text</u> field (not numeric), so that leading zeros are not inadvertently dropped.

6.3.   Data Format for EPCIS: URI Format

Within the EPCIS, SSCCs must be stored in EPC URI format. The EPC URI format for an SSCC is the SSCC EPC.

General syntax:

urn:epc:id:sscc:*CompanyPrefix.SerialReference*

Example:

urn:epc:id:sscc:0614141.1234567890

Grammar:

SSCC-URI ::= "urn:epc:id:sscc:" SSCCURIBody

SSCCURIBody ::= PaddedNumericComponent "."PaddedNumericComponent

The number of characters in the two PaddedNumericComponent fields must total 17 (not including any of the dot characters). Figure 7 depicts how the element string of an SSCC corresponds to the element string of a SSCC EPC URI:
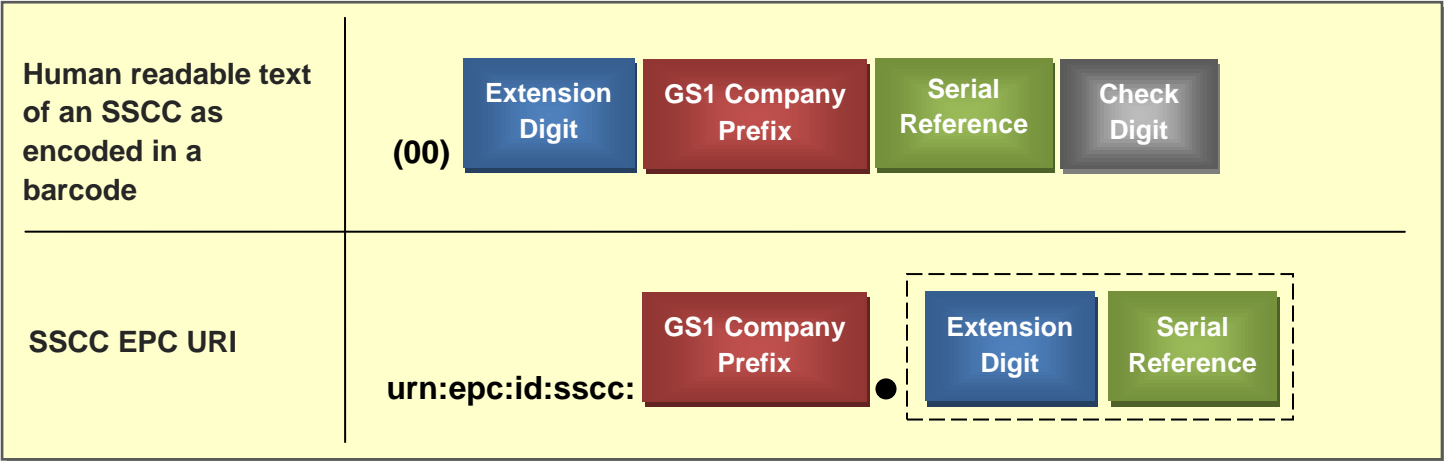
Figure 7: How the segments of an SSCC are represented in the SSCC EPC URI format

- The GS1 Company Prefix is the same as the GS1 Company Prefix digits within a GS1 SSCC key.
- The *Serial Reference* as it appears in the SSCC EPC URI is derived from the SSCC key by concatenating the Extension Digit of the SSCC and the Serial Reference digits, and treating the result as a single numeric string.
- The *Check Digit* is not used in the EPC URI format.

6.4.   Data Storage Options

When storing SSCCs in databases, they can be saved in their regular format, saved in the EPC URI format (to be parsed by backend systems as needed), or saved as both. Thus, there are three options for storing SSCC in databases:

1 field =	SSCC
1 field =	SSCC in EPC URI format
2 fields =	SSCC field and a field containing SSCC in EPC URI format

Select whichever method best serves your data storage strategies. The data format for each of those fields is provided in Table 5 below:

Field	Data Format
SSCC	18 digits - text field (not numeric, to avoid dropping leading zeros)
SSCC URI	34 characters - text field

Table E: Data Formats for SSCC Fields

7. Identifying Parties & Locations: GLN

In the GS1 System, parties and locations are identified with the Global Location Number (GLN). The GLN is a 13-digit, globally unique, standards-based, identification number for legal entities, functional entities, and physical locations. Each company is responsible for assigning (*allocating*) GLNs to its own parties and locations. When a user assigns a GLN, they define a prescribed set of data about the party/location to which that GLN relates (e.g., street address, floor, etc.). These GLN attributes define master data about the party/location (e.g., name, address, class of trade, etc.), which help to ensure that each GLN is specific to one, very precise location within the world. The GLN and its associated attributes are then saved in a database (like the GLN Registry for Healthcare) and shared among supply chain partners.

ⓘ *GS1 US offers an annual GLN subscription program for companies that are not members of GS1 US and need only one or a few GLNs (e.g., wholesalers, distributors, and retailers without private label products). Subscribers to the GLN Registry for Healthcare have the option of acquiring GLNs using this GS1 US subscription program instead of allocating them as described above. Please call GS1 US Customer Service for more information about this program at +1 937.610.4222.*

7.1.   Assigning GLNs

Each GLN is a numerical string comprising three distinct segments. The three segments within a GLN are:

- **GS1 Company Prefix:** A globally unique number assigned to a company/organization by GS1 US to serve as the foundation for generating GS1 identifiers (e.g., GTINs; SSCCs; etc.). GS1 Company Prefixes are assigned in varying lengths depending on the company/organization's needs.

- **Location Reference:** A number assigned by the holder of the GS1 Company Prefix to uniquely identify a location within the company. The length of the *Location Reference* varies as a function of the GS1 Company Prefix length.

- **Check Digit:** A one-digit number calculated from the first 12 digits of the GLN used to ensure data integrity. GS1 US provides a check digit calculator to automatically calculate check digits for you. The check digit calculator can be found at http://www.gs1us.org/resources/tools-and-services/check-digit-calculator . (Check digits can also be calculated manually.)

Although the length of the GS1 Company Prefix and the length of the Location Reference vary, they will always be a combined total of 12 digits in a GLN. The addition of the *Check Digit* completes the 13 digits of the GLN. Figure 8 provides a color-coded example of a hypothetical GLN, and a key explaining how each digit is populated. (Figure 8 uses hypothetical GLN **0321012345676**.)

Example of a GLN													
GLN	0	3	2	1	0	1	2	3	4	5	6	7	6
Digit/Position	1	2	3	4	5	6	7	8	9	10	11	12	13

How to Populate Each Digit *(color-coded to coordinate with the GLN shown above)*

Positions 1 through 12	GS1 Company Prefix as assigned by GS1 US plus Location Reference number as assigned by the owner of the GS1 Company Prefix
Position 13	Check Digit

Figure 8: Populating the 13 digits of a GLN

7.2. Assigning GLN Extensions

GLN Extensions are used to identify internal physical locations within a location that is identified with a GLN. Locations that currently have a GLN may use GLN Extensions to distinguish unique sub-locations within that GLN location (e.g., production line, RFID tunnel, loading dock, etc.) GLN Extensions are represented by AI(254).   The GS1 General Specifications define a GLN Extension as an alphanumeric string whose length is variable between one and 20 characters (the specific characters allowed are defined in the GS1 General Specifications). GLN Extensions can be encoded in GS1 DataBar, GS1-128 and EPC/RFID tags. AI(254) may only be used in conjunction with AI(414) [i.e., GLN of a physical location].

Use of GLN Extensions is optional. Sub-locations can be identified by assigning a unique GLN to the sub-location, or by using a GLN Extension with the location's GLN. There is no rule for when to assign a new GLN versus when to use a GLN Extension. However, the GLN Workgroup has identified the following Best Practices to assist companies in making this decision:

- For sub-locations that will never be used as an address (e.g., shelf, door, etc.), use GLN Extensions in order to conserve GLNs.

- For sub-locations where the identifier will be used for purposes other than EPCIS events (e.g., EDI), assign a unique top-level GLN to that sub-location.

(For additional information, consult the GLN Workgroup materials.)

7.3. Data Format for Databases

In databases, GLN fields should be 13 digits in length. The GLN should be represented in a database as a <u>text</u> field (not numeric). The GLN extension should be represented in a database as a text field capable of handling from one to 20 characters.

7.4. Data Format for EPCIS: URI Format

Within the EPCIS, GLNs must be stored in EPC URI format. The EPC URI format for a GLN (with or without Extension) is the Serialized Global Location Number EPC (SGLN EPC).

General syntax:

urn:epc:id:sgln:*CompanyPrefix.LocationReference.Extension*

Example:

urn:epc:id:sgln:0614141.12345.400

Grammar:

SGLN-URI ::= "urn:epc:id:sgln:" SGLNURIBody

SGLNURIBody ::= PaddedNumericComponent "."

PaddedNumericComponentOrEmpty "." GS3A3Component

The number of characters in the two PaddedNumericComponent fields must total 12 (not including any of the dot characters). The Extension field of the SGLN-URI is expressed as a GS3A3Component, which permits the representation of all characters permitted in the AI (254) Extension according to the GS1 General Specifications. Figure 9 depicts how the element string of a GLN corresponds to the element string of an SGLN EPC URI:

- The GS1 Company Prefix is the same as the GS1 Company Prefix digits within a GS1 GLN key.

- The *Location Reference* is the same as it appears in the GLN key.

- The *Check Digit* is not used in the EPC URI format.

- The *Extension* is the same as the *GLN Extension* assigned by the managing entity to an individual unique location. <u>If there is no GLN Extension for this location, enter a single zero digit to indicate that the SGLN stands for a GLN without an extension</u>.
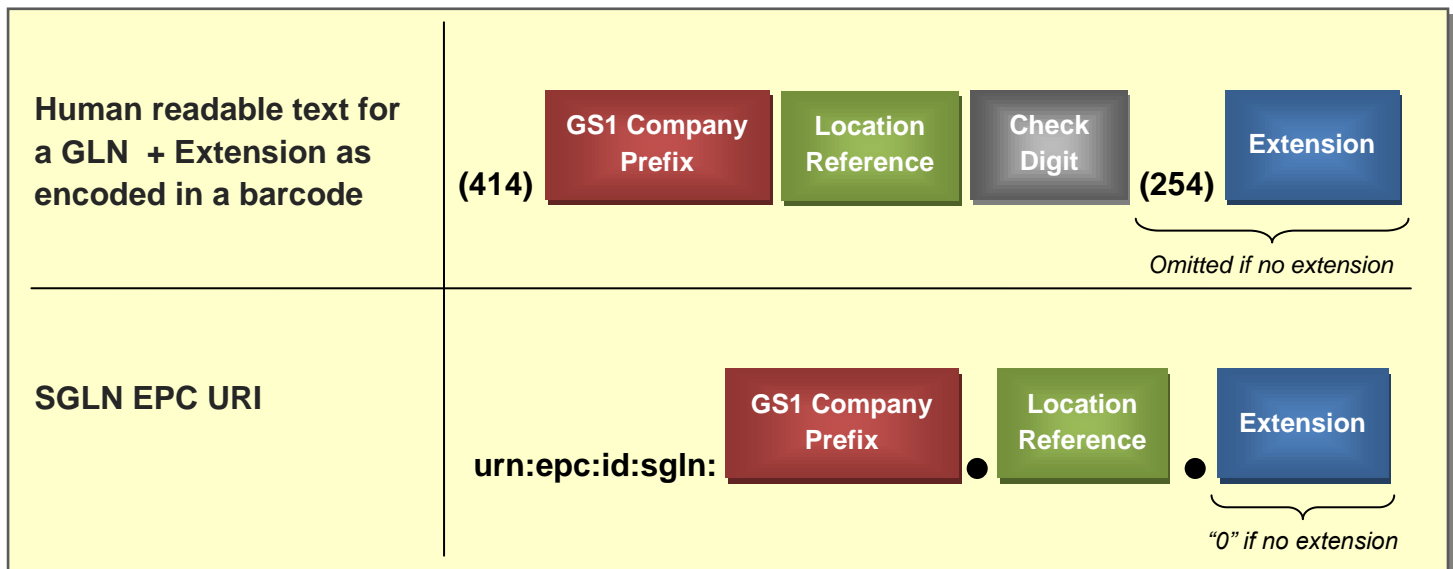
Figure 9: How the segments of a GLN (with or without extension) are represented in the SGLN EPC URI format

7.5.   Data Storage Options

When storing SGLNs in databases, they can be saved in their regular format, saved in the EPC URI format (to be parsed by backend systems as needed), or saved as both. Thus, there are three options for storing a GLN with extension in databases:

2 fields =	GLN field and GLN Extension field
1 field =	One field containing GLN + extension in EPC URI format
3 fields =	GLN field, GLN Extension field, and field containing GLN + extension in EPC URI format

Select whichever method best serves your data storage strategies. The data format for each of those fields is provided in Table 6 below:

Field	Data Format
GLN	13 digits - text field (not numeric)
GLN Extension	1-20 characters - text field (not numeric)
SGLN EPC URI	31-50 characters: 16 characters for "urn:epc:id:sgln:" 12 characters for the GLN (no Check Digit) 1-20 characters for the GLN extension 2 periods ('.') - text field (not numeric)

Table F: Data Formats for GLN Fields

Part 3: Capture

GS1 Data Carriers provide *machine-readable representations* of GS1 Identification Numbers that facilitate automatic identification and data capture. In order to accommodate a variety of environments and applications, the GS1 System supports eight data carriers: six barcode symbologies (i.e., GS1 Barcodes) and two RFID tags (i.e., GS1 EPC/RFID Tags).

Table 7 lists the GS1 data carriers used in this guideline to support pedigree and track and trace. Because this guideline documents a specific application of the standards to support serialization and pedigree, only data carriers that can carry serial numbers are shown.

Supply Chain Object	GS1 Data Carrier Options
TRADE ITEMS: Products, Cases & Kits	GS1 DataMatrix
	GS1-128
	EPC/RFID Tag
LOGISTICS UNITS: Cases, Pallets & Totes	GS1-128
	GS1 DataMatrix
	EPC/RFID Tag

Table G: GS1 Data Carriers Used in this Guideline

8. Encoding GS1 Data Carriers

Examples in this guideline use four GS1 Data Carriers: three GS1 barcodes and one EPC/RFID tag. Guidance for encoding those data carriers is provided in this chapter.

8.1.   Barcodes

The data elements within a barcode are demarcated through the use of GS1 Application Identifiers (AIs). GS1 AIs are a finite set of specialized identifiers encoded within barcodes to indicate the type of data represented in the various barcode segments. Each AI is a two, three, or four digit numeric code. (When rendered in human-readable form, the AI is usually shown in parentheses. However, the parentheses are not part of the barcode's encoded data.) Each data element in a barcode is preceded by its AI. There are approximately 100 AIs, including one AI for each GS1 identifier (e.g., GTIN, GLN, SSCC, etc.) as well as numerous AIs for secondary information. The AI's that are relevant to this guideline are:

AI (01)	GTIN		AI (21)	Serial Number
AI (00)	SSCC		AI (10)	Batch/Lot Number
AI (414)	GLN (physical location)		AI (17)	Expiration Date
AI (254)	GLN Extension			

More than one AI can be carried in one barcode. Table 8 presents some high-level concepts and principles that should be followed when encoding barcodes.

Principle	Example/Illustration
Each barcode data element has a two- to four-digit AI that defines data type and field size.	GTIN **AI(01)** Serial Number **AI(21)** Batch/Lot Number **AI(10)** Expiration Date **AI(17)** SSCC **AI (00)**
When encoding, each data element is preceded by its corresponding AI.	GTIN **(01)00314141999995** Expiration Date **(17)101231** Batch/Lot Number **(10)987654321GFEDCBA** Serial Number **(21)ABCDEFG123456789** SSCC **(00)003345678912345604**
Encode the GS1 Identifier (GTIN or SSCC) first. Encode any optional data (such as batch/lot number, expiration date, serial number, etc.) following the identifier. NOTE: *Although parentheses and spaces appear in the human readable text accompanying the barcode, these characters are not encoded in the barcode itself.*	 (01) 00314141999995 (10) 987654321GFEDCBA
For the most efficient encoding, ensure that fixed- length AI's precede variable-length AI's.	 (01) 00314141999995 (17) 101231 (10) 987654321GFEDCBA (21) 123456789ABCDEFG GTIN *fixed* Expiration Date *fixed* Batch/Lot Number *variable* Serial Number *variable*

Table H: Encoding Principles

ⓘ **Human Understandable Text Below A Barcode:** *Many pharmaceutical companies are including text below the barcode that is more readily understandable by healthcare clinicians and supply chain personnel. Here are some examples:*

GTIN 00314141999995
SN   10000000234
LOT 987654321GFEDCBA
EXP 01/2015

GTIN 00314141999995
SN   10000000234
EXP JAN 2015
LOT 987654321GFEDCBA

GTIN 00314141999995
SN   10000000234
EXP 25 JAN 2015
LOT 987654321GFEDCBA

8.1.1. Trade Items: Products, Cases & Kits

As a way of gaining uniformity throughout the supply chain, this guideline includes two best practice barcode options for products, cases and kits: GS1 DataMatrix and GS1-128. There are two required data elements to be encoded: GTIN and Serial Number.

Barcodes for Products, Cases & Kits		
Required Identification Information	Data Element	Corresponding GS1 AI
	GTIN	AI (01)
	Serial Number	AI 21)
GS1 Barcode Options	GS1 DataMatrix GS1-128	

Table I: Barcodes for Products, Cases & Kits

Encoding Principles:

GTIN
- Begin with the two-digit AI (01) to indicate GTIN.
- A fixed-length field comprising the 14 numeric characters of a GTIN data follows the AI.
   - ⓘ *For GTIN-12: encode in 14-digit format using two leading zeros*
- The data syntax for the GTIN component is n2 + n14.
- **EXAMPLE: 0100312345678906**

Serial Number
- The two-digit AI **(21)** is used to indicate the *Serial Number*.
- A variable-length field of up to 20 alphanumeric characters of *Serial Number* data follows the AI.
   - ⓘ *If using a barcode with a 96-bit EPC/RFID tag: see Section 5.2 for limitations on serial number*
- The data syntax for the *Serial Number* component is n2 + a1..20.
- **EXAMPLE: 21ABCDEFG123456789**

Examples:

Figure 10: GTIN with Serial Number Encoded in a GS1 DataMatrix

(01) 00314141999995
(21) 123456789ABCDEFG

Figure 11: GTIN with Serial Number Encoded in a GS1-128

(01) 00314141 999995 (21) ABCDEFG123456789

ⓘ **Marking Products with Both UPC-A and GS1 DataMatrix**

Many pharmaceutical manufacturers are marking products that move through a Point of Sale (POS) with both a UPC-A <u>and</u> a GS1 DataMatrix:

- ▪ *Any item that passes through a POS is typically marked with a UPC-A. The UPC-A is a linear barcode that holds a maximum of 12 digits, which promotes readability by traditional POS systems. The UPC-A can be used to satisfy the FDA's linear barcode requirement. However, because it is limited to 12 digits, the UPC-A cannot carry the information needed to satisfy serialization and/or pedigree requirements.*

- ▪ *The GS1 DataMatrix is a 2D barcode that can carry more data (e.g., GTIN, serial number, expiration date, etc.) in a smaller space. Most manufacturers are choosing to use the GS1 DataMatrix to satisfy serialization and/or pedigree requirements. However, as a 2D barcode, the GS1 DataMatrix does not satisfy the FDA's linear barcode requirement.*

Marking pharmaceutical products that cross POS with both barcodes satisfies both types of requirements (i.e., the UPC-A for the FDA linear barcode requirement, and the GS1 DataMatrix for serialization/pedigree requirements). To ensure that the GTIN encoded in both barcodes is the same, manufacturers should follow the recommendations outlined in Section 4.5 for all products that will be marked with both a UPC-A and a GS1 DataMatrix.

GTIN-12 encoded in a UPC-A

GTIN-12 encoded in a GS1 DataMatrix

8.1.2. Logistics Units: Pallets, Cases & Totes

This guideline includes two barcode options for pallets, cases and totes: GS1-128 and GS1 DataMatrix. There one required data element to be encoded: SSCC.

Cases Pallets & Totes		
Required Identification Information	Data Element	Corresponding GS1 Standard
	SSCC	AI (00)
GS1 Barcode Options	GS1-128 GS1 DataMatrix	

Table J: Barcodes for Pallets, Cases & Totes

Encoding Principles:

SSCC
- The two-digit AI (00) is used to indicate SSCC.
- A fixed-length field comprising the 18 numeric characters of SSCC data follows the AI.
- The data syntax for the SSCC component is n2 + n18.
- **EXAMPLE: 00003345678912345604**

Examples:

Figure 12: SSCC Encoded in a GS1-128

(00) 0 0314141 000098765 7

Figure 13: SSCC Encoded in a GS1 DataMatrix

(00) 0 0314141 000098765 7

8.2.   EPC/RFID Tags

EPC/RFID tags use a specialized binary encoding to hold data equivalent to barcode data. Software that reads and writes EPC/RFID tags translates between this binary encoded form and the barcode form (and/or the EPC URI form). See the *EPC Tag Data Standard* for details about how the translations are performed.

9. Translating Captured Data

The EPCIS stores identifiers (e.g., GTIN + serial number; SSCC; GLN; etc.) in EPC URI format, which differs from both the AI-based format used in GS1 barcodes and the binary encoding used in EPC/RFID tags. Therefore, identification information read from either barcodes or EPC/RFID tags must first be translated into EPC URI format in order to be stored in the EPCIS.

Most commercial RFID and/or EPCIS products already have the translation technology integrated into their software so that data read from either barcodes or EPC/RFID tags is automatically translated into EPC URI format when an EPCIS event is created. However, if a company is implementing their own software, they can either write their own translation module or license one of the commercially-available software libraries on the market.

In order to translate barcode data into EPC URI format, it is necessary to know the length of the GS1 Company Prefix (i.e., what is the length of the GS1 Company Prefix in this barcoded GTIN?). To facilitate this, GS1 US has published a table of U.S. GS1 Company Prefixes (www.gs1us.org/gcplist) that you can download and link to your translator/EPCIS to enable your system to access GS1 Company Prefix lengths automatically instead of prompting the user for the information. Alternatively, you can ask your trading partners for the length of their GS1 Company Prefixes and create your own table. (NOTE: EPC/RFID tags already include the length of the GS1 Company Prefix in the encoded binary form. Therefore, no additional lookup is needed to translate binary data from EPC/RFID tags into EPC URI format.)

9.1. EPC URI Format for GTIN + serial number

The EPC URI format for a GTIN + serial number is the Serialized Global Trade Item Number EPC (SGTIN EPC).

General syntax:

urn:epc:id:sgtin:*CompanyPrefix.ItemReference.SerialNumber*

Example:

urn:epc:id:sgtin:0614141.112345.400806

Grammar:

SGTIN-URI ::= "urn:epc:id:sgtin:" SGTINURIBody

SGTINURIBody ::= 2*(PaddedNumericComponent ".") GS3A3Component

The number of characters in the two PaddedNumericComponent fields must total 13 (not including any of the dot characters). The Serial Number field of the SGTIN-URI is expressed as a GS3A3Component, which permits the representation of all characters permitted in the (AI) 21 Serial Number according to the GS1 General Specifications. Figure 14 depicts how the element string of a GTIN + serial number corresponds to the element string of a SGTIN EPC URI:

- The GS1 Company Prefix is the same as the GS1 Company Prefix digits within the GTIN key.
- The *Item Reference* as it appears in the SGTIN EPC URI is derived from the GTIN key by concatenating the Indicator Digit of the GTIN and the Item Reference digits, and treating the result as a single numeric string.

- The *Check Digit* is not used in the EPC URI format.
- The *Serial Number* is the equivalent of AI(21).

| Human readable text of GTIN + Serial Number as encoded in a barcode | **(01)** | Indicator Digit | GS1 Company Prefix | Item Reference | Check Digit | **(21)** | Serial Number |
| SGTIN EPC URI | **urn:epc:id:sgtin:** | GS1 Company Prefix | Indicator Digit | Item Reference | | | Serial Number |
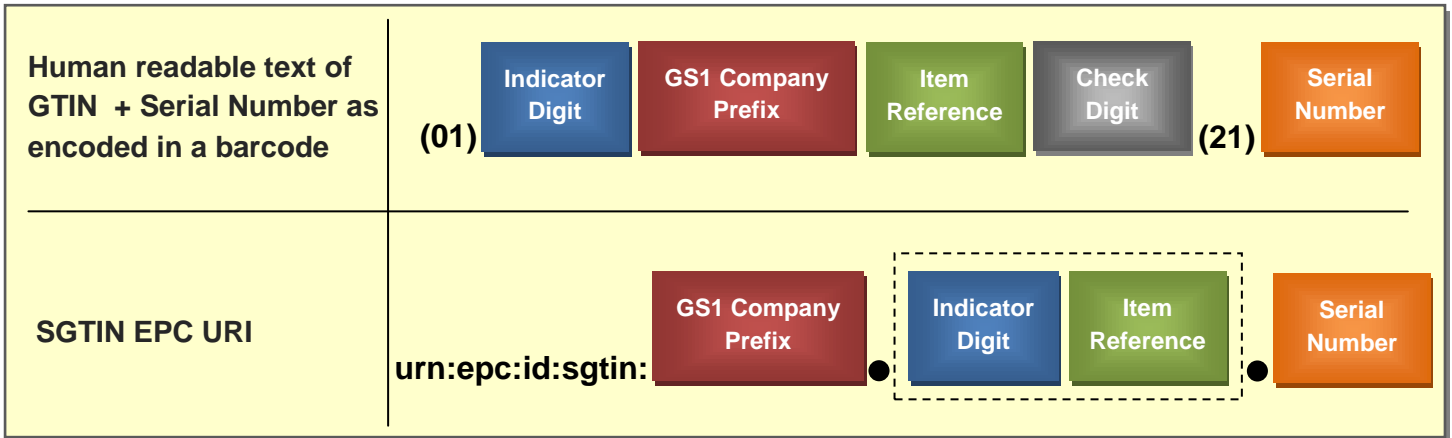
Figure 14: How the segments of a GTIN + serial number are represented in the SGTIN EPC URI format

Example – Converting a GTIN-14 + Serial Number into EPC URI Format:

GTIN-14	2 030001 123498 7
Serial Number	123456789012
Corresponding Barcode human readable text	(01) 2 030001 123498 7 (21)123456789012
Corresponding SGTIN EPC URI	urn:epc:id:sgtin: 030001 . 2 123498 . 123456789012

ⓘ *The spaces in the examples above have been inserted for visual clarity. Those spaces are not included in either the GTIN-14 or the SGTIN EPC URI actually used within a computer system.*

9.2.   EPC URI Format for SSCC

General syntax:

urn:epc:id:sscc:*CompanyPrefix*.*SerialReference*

Example:

urn:epc:id:sscc:0614141.1234567890

Grammar:

SSCC-URI ::= "urn:epc:id:sscc:" SSCCURIBody

SSCCURIBody ::= PaddedNumericComponent "."PaddedNumericComponent

The number of characters in the two PaddedNumericComponent fields must total 17 (not including any of the dot characters).

Figure 15 depicts how the element string of an SSCC corresponds to the element string of a SSCC EPC URI:

- The GS1 Company Prefix is the same as the GS1 Company Prefix digits within a GS1 SSCC key.

- The *Serial Reference* as it appears in the SSCC EPC URI is derived from the SSCC key by concatenating the Extension Digit of the SSCC and the Serial Reference digits, and treating the result as a single numeric string.

- The *Check Digit* is not used in the EPC URI format.
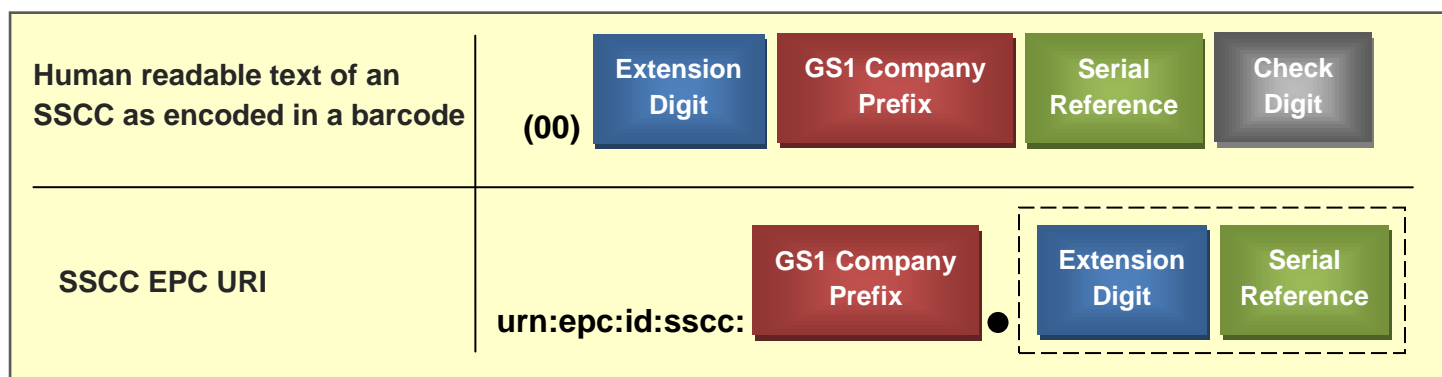
Figure 15: How the segments of an SSCC are represented in the SSCC EPC URI format

9.3. Data Storage Options

When storing GTIN + serial number in databases, GTINs and serial numbers can be saved in their own fields, saved together in the EPC URI format (to be parsed by backend systems as needed), or saved as both. Thus, there are three options for storing GTINs and serial numbers in databases:

2 fields =	GTIN field and Serial Number field
1 field =	One field containing serialized GTIN in EPC URI format
3 fields =	GTIN field, Serial Number field, and field containing serialized GTIN in EPC URI format

Select whichever method best serves your data storage strategies. The data format for each of those fields is provided in Table 11 below:

Field	Data Format
GTIN	- 14 digits - text field (not numeric)
Serial Number	- 1-20 characters - text field (not numeric)
Serialized GTIN EPC URI	- 33-52 characters: - 17 characters for "urn:epc:id:sgtin:" - 13 characters for the GTIN (without the Check Digit) - 1-20 characters for the serial number - 2 periods (".") - text field (not numeric)

Table K: GTIN+ serial number Data Formats

When storing SSCCs in databases, they can be saved in their regular format, saved in the EPC URI format (to be parsed by backend systems as needed), or saved as both. Thus, there are three options for storing SSCC in databases:

1 field =	SSCC
1 field =	SSCC in EPC URI format
2 fields =	SSCC and a field containing SSCC in EPC URI format

Select whichever method best serves your data storage strategies. The data format for each of those fields is provided in Table 12 below:

Field	Data Format
SSCC	▪ 18 digits ▪ text field (not numeric, to avoid dropping leading zeros)
SSCC EPC URI	▪ 34 characters ▪ text field (not numeric)

Table L: SSCC Data Formats

Part 4: Share Concepts

10. Master Data

When users assign a GS1 Identification Number, they define a set of standardized information (known as *attributes*) about the object to which that identifier relates. The GS1 System specifies the list of attributes that must be defined for each GS1 Identifier, and provides a precise definition as well as acceptable values and data formats for each attribute. This set of attributes constitutes the "master data" about the object. For example:

- The GTIN is the globally unique GS1 Identification Number used to identify products. Standardized GTIN attributes about products include selling unit, item dimensions, and product classification. Once defined by the user, those attributes are then stored in a GDSN-certified Data Pool and shared with supply chain partners using the Global Data Synchronization Network (GDSN).

- The GLN is the globally unique GS1 Identification Number for locations and supply chain partners. Standardized GLN data about locations include name, street address, location type, etc. Once defined by the user, those attributes are then stored in a database and shared with supply chain partners using the GLN Registry.

From there, GS1 Identification Numbers can be encoded into GS1 Data Carriers for identification and automatic data capture, and used in supply chain transactions. Because of this, master data, transaction data, and event data related to supply chain objects are all connected by their GS1 Identification Number.

GS1 Identification Numbers provide a link to information, and GS1 Standards for data sharing enable supply chain partners to share data and link it up in their systems to avoid re-entering it for every application that needs the data:

Sharing Master Data	Products = GDSN, RxNorm, Prime Vendor Database Locations = GLN Registry for Healthcare
Sharing Event & Disposition	EPCIS
Item Event Locator	Discovery Services

This is especially important for EPCIS applications like pedigree where trading partners capture and share information about numerous supply chain events for each product. Use of GS1 Identifiers minimizes the data collected for each event, and maximizes the data that can be linked to the event. This enables trading partners to avoid massive duplication of data in their systems by managing master data separately from pedigree data. For example, a distributor records a Pedigree Event. The *Object ID* (i.e., GTIN) provides the link to finding master data about the product:

> **Name:** Product X, 50 Tabs

The *BizLocation* (i.e., GLN) provides the link to master data about the location using the GLN Registry:

> **LocationName:** Smithfield Distribution Center
> **Address:** 123 Main Street
> **City:** Lawrenceville
> **State:** NJ
> **Zip Code:** 08648

Best Practices:

- Because master data is managed separately from event/pedigree data, it is essential to archive the original/previous version of master data whenever master data about products or locations is updated or changed. This will ensure that the historic master data is still available if ever needed after the update.

- Need to validate and establish the source and governance of your master data.

ⓘ *The following documents provide an in depth discussion of Master Data Management concepts (see Section 2.6 for links):*

- *Healthcare Provider GTIN Tool Kit*
- *Healthcare Supplier GTIN Tool Kit*
- *Healthcare Provider GLN Tool Kit*
- *Healthcare Supplier GLN Tool Kit*
- *Healthcare Provider GDSN Tool Kit*
- *Healthcare Supplier GDSN Tool Kit*

11. Event Data

Electronic Product Code Information Services (EPCIS) is a GS1 Standard for capturing and communicating data about the movement and status of objects in the supply chain (e.g., products; logistics units; returnable assets; etc.). It enables supply chain partners to capture event information about objects as they move through the supply chain (e.g., shipped; received; etc.), and to share that information with their trading partners securely and in near real-time. EPCIS defines technical standards for a data-sharing interface between applications that capture EPC-related data and those that need access to it. EPCIS also provides data standards for how to express what business process was operating on the object and the status of the object upon exiting the process. For the data standards, EPCIS makes use of a second standard named the Core Business Vocabulary (CBV), which offers a pre-defined vocabulary for a large set of business events and scenarios.

The data elements captured and recorded for each EPCIS event are grouped into four dimensions: *what*, *when*, *where*, and *why*. The GS1 General Specifications and the GS1 EPC Tag Data Standard define identifiers for physical objects used in the "*what*" dimension, and identifiers for locations used in the "*where*" dimension. The GS1 EPC Core Business Vocabulary provides lists of acceptable values for *Business Step, Disposition*, and *Business Transaction Type* used in the *why* dimension, as well as the format for the business transaction identifiers used in the *why* dimension. Beyond the four dimensions of *what*, *where*, *when*, and *why* defined in the EPCIS standard, this guideline defines extension fields used to provide additional business data for ePedigree in certain EPCIS events.

The data elements captured and recorded for each EPCIS are presented in Table 13 below.

Dimension	Data	Definition	Examples
	Event Type Action	the event type and the action together define the type of EPCIS event; e.g., object creation, object observation, aggregation, disaggregation, etc	Object Event with Action = ADD Aggregation Event with Action = DELETE etc.
What	**EPC List**	the item's GS1 Identification Key, expressed as an EPC Pure Identity URI. Depending on the event type, this will either be a list of EPCs, or the combination of a Parent ID and a list of child EPCs	GTIN, SSCC, GRAI, etc.
	Parent ID		
	Child EPCs		
When	**Event Time**	the moment in time at which the event occurred	March 15, 2010 at 10:07am UTC
	Event Timezone Offset	indicates the local time zone in effect at the place where the event occurred. This is not needed to interpret Event Time (which carries its own timezone indicator) but instead helps software display data to users in local time	UTC -05:00
Where	**Read Point**	the location at which the event took place, expressed as an EPC Pure Identity URI	GLN or GLN with extension
	Business Location	the location at which the objects are presumed to be following the event until a subsequent event says otherwise, expressed as an EPC Pure Identity URI	GLN or GLN with extension
Why	**Business Step**	the business process taking place at the time of this event	Shipping, Receiving, Picking, etc.
	Disposition	business condition of the objects named in the *what* dimension that is presumed to hold until a subsequent event occurs	Saleable, Recalled, etc.
	Business Transaction	one or more references to associated business transactions, each comprised of a business transaction type (e.g., purchase order, invoice, etc) and a globally unique reference to a specific transaction of that type	Acme Corp Purchase Order #1234

Table M: EPCIS Data

EPCIS is a flexible standard that can be leveraged for a wide variety of business needs. To serve the needs of a particular business application, supply chain partners must come to an agreement with regard to the EPCIS events and data that will be shared. Therefore, members of the U.S. pharmaceutical industry joined forces to determine how the EPCIS shall be applied to support pedigree and track and trace.

The remainder of this document specifies how the EPCIS standard is applied to support pedigree and track and trace for the US pharmaceutical industry.

Part 5: Application of EPCIS for Serialized Product Pedigree

EPCIS events consist of data captured by each party in the supply chain as they handle a product in the course of the product's lifecycle. As such, EPCIS events provide visibility of handling operations for either internal business applications (i.e., if the EPCIS events are consumed internally), or across the supply chain (i.e., if the events are shared with trading partners). Visibility data in the form of EPCIS events may be used to automate a variety of business processes, including track and trace, pedigree, recall, etc.

This section specifies the minimum set of EPCIS events required to support the pedigree business process. A set of EPCIS events pertaining to a specific instance or instances of a product, inclusive of all events from the point of origin (i.e., commissioning) to the present, and conforming to this section provides all of the data content in a drug pedigree. Certain pedigree laws consider product and location data to be part of the pedigree.   Companies that have implemented the best practice of a Master Data Management architecture, may wish to obtain and manage product and location master data separate from the EPCIS events themselves. For example, a drug pedigree includes both the unique identifier for a pharmaceutical product (i.e., the NDC and/or GTIN), as well as its dose and strength information. When using EPCIS events to provide pedigree content, the NDC and/or GTIN is present in the EPCIS event data itself, while the dose and strength information is obtained from the master data associated with the NDC/GTIN. Those companies will use the product and location identifiers (GTIN and GLN, respectively) found in the EPCIS events as keys to "look up" the previously synchronized master data and assemble the full drug pedigree content.

Other trading partners who are unable to, or have yet to adopt a master data management strategy may require the product and location master data be provided as part of the EPCIS events. To support both scenarios, product and location master data attributes are shown as "optional" in the EPCIS events.

Supply chain parties may collect additional EPCIS events not required for pedigree but used for other business applications. These events are discussed in a Part 7 of this guideline.

12. Overview of EPCIS Events for Serialized Product Pedigree

For purposes of pedigree, each party in the supply chain must capture and share a certain set of EPCIS events. The EPCIS events that need to be captured and shared by each party depend on that party's position in the supply chain. An overview of EPCIS events for pedigree is provided below. Detailed definitions of each EPCIS event are specified in subsequent subsections.

Events captured and shared by the party at the beginning of the supply chain (e.g., manufacturer):

- **Commissioning Events (Section 17.1)** declaring that specified serial numbers have been introduced into the supply chain and providing information about the corresponding products.

- **Packing Events (Section 17.2)** providing the hierarchical relationships (e.g., item-to-case, case-to-pallet) between objects as they exist at the point of shipping. The beginning party does not need to reflect any internal unpacking and packing activity that may have taken place, as long as the events that are shared fully account for the hierarchy as shipped.

- **Shipping Events (Section 17.3)** indicating that objects have been shipped to a downstream trading partner and providing pedigree information governing the shipment. The shipping events only reference the outermost (i.e., top-level) products in the packaging hierarchy. The full hierarchy is specified by inference from the prior packing events.

Events captured and shared by intermediate parties (e.g., distributor):

- **Receiving Events (Section 17.4)** indicating that objects have been received from an upstream trading partner and providing pedigree information governing the receipt. The receiving party may only verify the identifiers of the outermost (i.e., top-level) products in the packaging hierarchy, in which case the full hierarchy inferred from prior packing events is inferred to have been received. Alternatively, the receiving party may verify one or more inner levels of hierarchy *(in which case the verified levels are declared explicitly in the receiving event, and inference is only used for inner levels not declared explicitly or not at all if all levels are declared explicitly)*.

- **Unpacking Events (Section 17.5), Commissioning Events (Section 17.1), and Packing Events (Section 17.2)** as needed to reflect changes in the packaging hierarchy that have occurred prior to shipment. Commissioning events in this instance are only used to introduce new identifiers for logistic units (e.g., new SSCCs for pallets packed to order), *not to introduce new products.* The intermediate party does not need to reflect all internal unpacking, commissioning, and packing activity that may have taken place, as long as the events that are shared fully account for all changes in hierarchy between receiving and shipping.

- **Shipping Events (Section 17.3)** indicating that objects have been shipped to a downstream trading partner and providing pedigree information governing the shipment. The shipping events only reference the outermost (i.e., top-level) products in the packaging hierarchy. The full hierarchy is specified by inference from the prior unpacking and packing events (possibly including unpacking and packing events from prior supply chain parties).

Events captured and shared by the party at the end of the supply chain (e.g., Hospital, Pharmacy, etc):

- **Receiving Events (Section 17.4)** indicating that objects have been received from an upstream trading partner and providing pedigree information governing the receipt. The receiving party may only verify the identifiers of the outermost (i.e., top-level) products in the packaging hierarchy, in which case the full hierarchy inferred from prior packing events is inferred to have been received. Alternatively, the receiving party may verify one or more inner levels of hierarchy *(in which case the verified levels are declared explicitly in the receiving event, and inference is only used for inner levels not declared explicitly or not at all if all levels are declared explicitly).*

- **Unpacking Events (Section 17.5) and Packing Events (Section 17.2)** as needed to reflect changes in the packaging hierarchy that have occurred prior to end-of-life events. The final party does not need to reflect all internal unpacking and packing activity that may have taken place, as long as the unpacking and packing events that are shared fully account for all changes in hierarchy between receiving and end-of-life events.

- **End-of-life events including Dispensing (Section 17.6.1), Destroying (Section 17.6.3), and Decommissioning (Section 17.6.4)** indicating that specific products have been removed from the supply chain

13. Pedigree Data Elements

Drug pedigree data elements are derived from both the data in the EPCIS events themselves, as well as certain product and location master data that is referenced by product and location identifiers found in the EPCIS event. For example, a drug pedigree includes both the unique identifier for a pharmaceutical product (i.e., the NDC and/or GTIN), as well as its dose and strength information. When using EPCIS events to provide pedigree content, the NDC and/or GTIN is present in the EPCIS event data itself, while the dose and strength information is obtained from the master data associated with the NDC/GTIN.

A list of the pedigree data elements (from GS1 / EPCglobal Pedigree Ratified Standard v1.0) with the expected source for that data is provided in Table 14 below.

Type of Information	Data Attribute	Expected Source (EPCIS Event, Master Data, etc.)
Document Information	Pedigree serial number	Event ID
Item Information	Item serial number(s) of product(s) (if available)	EPCIS epcList
	Lot number	EPCIS ObjectEvent event where bizStep is "commissioning"
	Expiration date	EPCIS ObjectEvent event where bizStep is "commissioning"
	Quantity of saleable units in transaction	EPCIS ObjectEvent event where bizStep is "shipping"

Type of Information	Data Attribute	Expected Source (EPCIS Event, Master Data, etc.)
Product Information	Drug name	Product Master Data
	Manufacturer	Product Master Data
	Product code (e.g., the NDC number)	EPCIS epcList and as part of the additionalTradeItemIdentification
	Dosage form	EPCIS ObjectEvent event where bizStep is "commissioning"
	Strength	EPCIS ObjectEvent event where bizStep is "commissioning"
	Container size	EPCIS ObjectEvent event where bizStep is "commissioning"
Transaction Information	Transaction identifier (for example, invoice or purchase order number)	EPCIS ObjectEvent event where bizStep is "shipping"
	Transaction document type (e.g., Invoice, Purchase order, Return authorization)	EPCIS ObjectEvent event where bizStep is "shipping"
	Date of transaction	EPCIS eventTime and eventTimeOffset
	Transaction type (e.g., sale, transfer, return)	EPCIS ObjectEvent event where bizStep is "shipping"
Seller and Recipient Information	Business Address (see below)	Location Master Data, or EPCIS ObjectEvent event where bizStep is "shipping" or "receiving"
	Shipping Address (see below; used only if different than Business Address)	Location Master Data, or EPCIS ObjectEvent event where bizStep is "shipping" or "receiving"
	License number	EPCIS ObjectEvent event where bizStep is "shipping"
	License state or region	EPCIS ObjectEvent event where bizStep is "shipping"
	License agency	EPCIS ObjectEvent event where bizStep is "shipping"
	Contact Information for seller used for authentication of transaction (see below)	EPCIS ObjectEvent event where bizStep is "shipping"
Business and Shipping Address	Business name	Location Master Data, or EPCIS ObjectEvent event where bizStep is "shipping" or "receiving"
	Street1	Location Master Data, or EPCIS ObjectEvent event where bizStep is "shipping" or "receiving"
	Street 2	Location Master Data, or EPCIS ObjectEvent event where bizStep is "shipping" or "receiving"
	City	Location Master Data, or EPCIS ObjectEvent event where bizStep is "shipping" or "receiving"
	State or Region	Location Master Data, or EPCIS ObjectEvent event where bizStep is "shipping" or "receiving"
	Postal Code	Location Master Data, or EPCIS ObjectEvent event where bizStep is "shipping" or "receiving"
	Country	Location Master Data, or EPCIS ObjectEvent event where bizStep is "shipping" or "receiving"

Type of Information	Data Attribute	Expected Source (EPCIS Event, Master Data, etc.)
Contact Information1	Contact Name	EPCIS ObjectEvent event where bizStep is "shipping"
	Contact Title	EPCIS ObjectEvent event where bizStep is "shipping"
	Contact Email	EPCIS ObjectEvent event where bizStep is "shipping"
	Contact Telephone	EPCIS ObjectEvent event where bizStep is "shipping"
	Contact URL (for automated authentication)	EPCIS ObjectEvent event where bizStep is "shipping"
Receiving Information	Date received	EPCIS ObjectEvent event where bizStep is "receiving"
	Item Information (e.g., Lot, Quantity, Serial Numbers) for items in partial receipt2	EPCIS ObjectEvent event where bizStep is "commissioning"
Signer Information	Name of signer	EPCIS ObjectEvent event where bizStep is "receiving"
	Title of signer	EPCIS ObjectEvent event where bizStep is "receiving"
	Date of signature	EPCIS ObjectEvent event where bizStep is "receiving"
	Signature meaning (defines certification context such as certified outbound, received and	EPCIS ObjectEvent event where bizStep is "receiving"
	authenticated inbound)	EPCIS ObjectEvent event where bizStep is "receiving"
Digital Signature Information3	SignedInfo	N/A
	SignatureValue	N/A
	KeyInfo	N/A
	SignatureProperties	N/A

Table N: Pedigree Data Elements

14. Pedigree Data Rules

14.1. EPCIS Event Time

The *Event Time* data element in an EPCIS event is defined as the moment in time when the event occurred. When sharing EPCIS events with trading partners for pedigree purposes, it is permissible for the *Event Time* to be different from the actual moment in time when the event occurred, provided that the rules in this section are followed. These rules are designed to give freedom to supply chain parties to capture the *Event Time* in a manner that is not overly burdensome and to hide certain internal business details from trading partners (e.g., the lag in time between packing a shipment and dispatching the shipment through the door), while at the same time ensuring that applications receiving EPCIS events will see a "reasonable" sequence of *Event Times*. When a party shares EPCIS events with a trading partner, the *Event Time* in those events shall conform to the following rules.

ⓘ *Note that the Event Time shared with trading partners may differ from the Event Time captured internally, so long as the rules are followed; that is, a party may keep more detailed Event Time for internal use, but modify the Event Time to obscure certain details not appropriate to share with trading partners.*

Rules:

- The *Event Time* shared with trading partners may differ from the *Event Time* captured internally. However, for any given event, the *Event Time* shared with trading partners shall be the same across all trading partners.

- EPCIS provides for millisecond precision in the *Event Time*. The *Event Time* shared with trading partners may be expressed with less precision, provided that the reported *Event Time* is within one minute of the actual *Event Time*.

- Business processes such as packing and shipping may take place over a span of time rather than a moment in time. Normally, the *Event Time* shared with trading partners should correspond to the time of completion of the process. However, any time within the span may be used as long as the other rules are adhered to.

- The diagram below shows the chronological sequence of *Event Times* that shall hold between events that refer to the same object identifier:

  - The *Event Time* reported for Shipping, Receiving, and end-of-life events shall reflect the true time of those events (subject to the rules above).

  - The *Event Time* for other events (e.g., commissioning, packing, unpacking) as shared with trading partners may be advanced in time up to (but not equal to) the time of the subsequent shipping or end-of-life event as long as the relationships in the diagram continue to hold.

  - Only the *Event Times* for Shipping, Receiving, and end-of-life events are relevant for pedigree purposes. The *Event Times* for other events may be advanced in order to obscure internal business details not relevant to trading partners.

Figure 16 below shows the relationships of *Event Times*. The " **<** " symbol indicates that the first *Event Time* must be strictly less than the second *Event Time.*
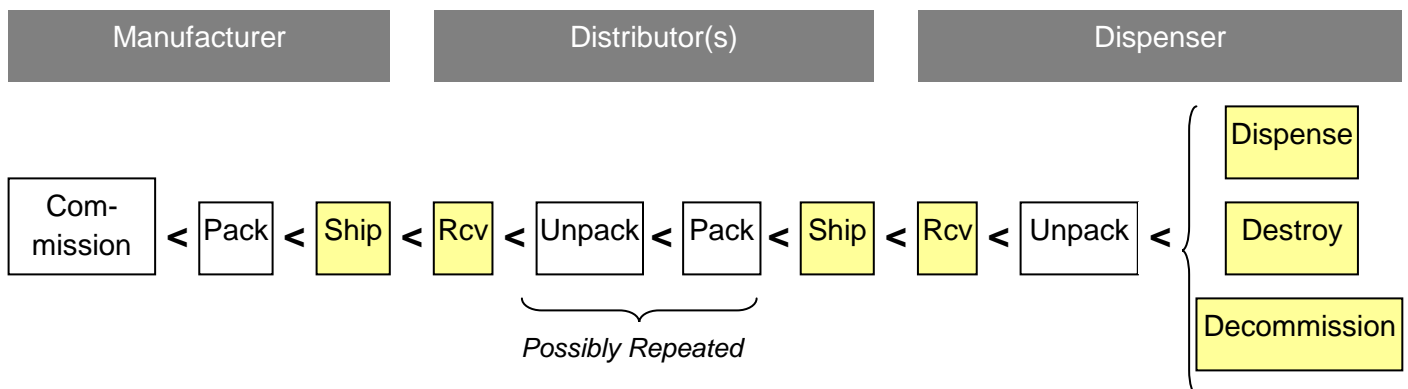
Figure 16: Event Time Relationships for Pedigree Purposes

Best Practice:

- For change of ownership situations where the process does not provide a natural change in time difference between shipping and receiving (consignment inventory), Receiving times Shall be created with a time greater than the related Shipping events (when used). When creating events to share with a trading partner, the timing of events should reflect the sequence of events that naturally would occur.

14.2. EPCIS Read Points and Business Locations

The EPCIS standard defines two data elements that provide the *where* dimension for an EPCIS event: *Read Point* and *Business Location*. The *Read Point* is an EPC URI that identifies the location where the event took place. The *Business Location* is an EPC URI that identifies the location where the object named in the event is presumed to be until a subsequent event says otherwise. The *Business Location* is useful for answering questions about where objects are right now (or at any prior moment between events).

Supply chain parties may capture *Read Points* and *Business Locations* at a coarse level (e.g., identifying a site or campus) or at a granular level (e.g., identifying a specific area or door within a building). A supply chain party may also choose to share location information with trading partners at a coarser level of granularity than it captures for internal purposes. For example, a supply chain party may capture the specific loading dock door where a shipping event took place for internal purposes. However, when sharing data with a trading partner, that party may only share the site without providing information about which dock door was used.

Rules:

EPCIS events shared for pedigree purposes shall conform to the following rules for *Business Locations* and *Read Points*:

- The *Business Location* for an event shall be a site-level GLN (without extension) expressed as an EPC URI. Such a URI begins with "**urn:epc:id:sgln:**" and ends with "**.0.**". (Note that *Business Location* is omitted from a Shipping event. See section 17.3.)

- The *Read Point* for an event shall be one of the following:

  o A site-level GLN (without extension) expressed as an EPC URI. . Such a URI begins with "**urn:epc:id:sgln:**" and ends with "**.0.**".

  o A GLN with extension denoting a more granular location within a site, expressed as an EPC URI. Such a URI begins with "**urn:epc:id:sgln:**" and ends with a dot followed by the GLN extension value. In this case, the base GLN shall be the same as the site-level GLN in which the more granular location is located.

    - For example, if you have used a GLN (GLN of: **urn:epc:id:sgln:**0354321654923.0) to identify a warehouse location and want to identify a location in the warehouse, use the warehouse's GLN and add an extension (**urn:epc:id:sgln:**0354321654923.1234).

ⓘ *GS1 Standards allow more granular locations within a site to be given individual GLNs without extension. However, the above rule requires that extensions be used in this case so that applications to ascertain the GLN for the site-level location can be accomplished by simply disregarding the extension.*

14.3.   EPCIS Business Transactions

The *Business Transaction* list in EPCIS events is used for purchase order and invoice information to be included in shipping and receiving events. The EPCIS standard specifies that *Business Transactions* be globally unique identifiers expressed in URI syntax.

Rules:

Business Transactions in EPCIS events shall conform to the following rules:

- The *Business Transaction* <u>type</u> shall be one of the URIs defined in Section 7.3 of the GS1 EPC Core Business Vocabulary. Typically, this is either **urn:epcglobal:cbv:btt:po** denoting a purchase order or **urn:epcglobal:cbv:btt:inv** denoting an invoice.

- The *Business Transaction* <u>identifier</u> shall conform to the syntax defined in Section 8.4.2 of the GS1 EPC Core Business Vocabulary. This syntax constructs a globally unique identifier in URI syntax by combining the transaction identifier (e.g., purchase order number) with a GLN that identifies the party that issued the transaction identifier. This combined identifier is globally unique and leaves no ambiguity about the system from which a transaction identifier comes. For example, urn:epcglobal:cbv:bt:0614141123452:A123 identifies a transaction whose native identifier (e.g., purchase order number) is A123 and which comes from a party identified by GLN 0614141123452.

- The GLN used in a *Business Transaction* identifier as specified above shall match the GLN provided in the **transferredById** or **transferredToId** extension to a shipping or receiving event (whichever party created the transaction). Namely, the *Business Transaction* identifier shall match the **transferredById** for an invoice, and the **transferredToId** for a purchase order. (See Section 17.3 for the definition of transferredById and transferredToId.)

14.4.   Checking EPCIS Event Contents

The following are suggested rules for verifying matching Receiving events and Shipping events.

- Pay attention to the dates. Dates should match your business expectations. Your systems should alert you to events outside of your normal business practice.

- The GTIN in the barcode should match the GTIN in the Shipping event.

- NDC in Receiving should match the Shipping NDC.

- All events SHALL conform to the attributes / extensions that are outlined in this guideline.

- Mandatory attributes SHALL exist.

- Location Identifier should belong to the expected party.

15. EPCIS Extension Elements

The EPCIS standard provides for data elements not specified in the standard to be included in EPCIS events as extensions. This is done by including additional XML elements just before the closing tag for an event, where those XML elements are in an XML namespace other than the EPCIS namespace.

All extension elements defined in this guideline are defined in the following XML namespace:

http://epcis.gs1us.org/hc/ns

All XML illustrations in this guideline use the prefix "gs1ushc" to denote this XML namespace. This means that an extension would look like this:

```
<epcis:EPCISDocument xmlns:gs1ushc="http://epcis.gs1us.org/hc/ns" ...>
  <EPCISBody>
    <EventList>
      <ObjectEvent>
        <eventTime>...</eventTime>
        ...
        <bizTransactionList>
          ...
        </bizTransactionList>
        <gs1ushc:lotNumber>ABC123</gs1ushc:lotNumber>
        <gs1ushc:itemExpirationDate>2011-03-15</gs1ushc:itemExpirationDate>
      </ObjectEvent>
    </EventList>
  </EPCISBody>
</epcis:EPCISDocument>
```

ⓘ *The EPCIS standard XML schema defines an element* `<extension>`. *This is reserved for use by future versions of the EPCIS standard to introduce new standard data elements in a forward-compatible way, and may not be used to define extensions outside of the EPCIS standard. Extensions outside the standard are defined as illustrated above (i.e., in a different XML namespace and not enclosed in the* `<extension>` *element).*

16. Core Business Vocabulary (CBV) Extensions

The EPCIS standard specifies that the *Business Step*, *Disposition*, and *Business Transaction Type* fields of EPCIS events shall be populated with URI strings (each denoting a specific business step, disposition, or business transaction type, respectively). The GS1 EPC Core Business Vocabulary (CBV) standard provides standardized URI strings for a variety of commonly-occurring *Business Steps*, *Dispositions*, and *Business Transaction Types*.

This guideline has identified the need for additional *Business Steps* and *Dispositions* in pedigree EPCIS events for which the CBV does not provide a suitable standardized identifier. This guideline specifies URI strings to use in these situations. All such URI strings have the following form:

For business steps:

`http://epcis.gs1us.org/hc/bizstep/`*`new-bizstep-name`*

For dispositions:

`http://epcis.gs1us.org/hc/disp/`*`new-bizstep-name`*

The specific names are specified in the sections documenting the events in which they are used.

> ⓘ *All vocabulary values beginning with* `urn:epcglobal:cbv:` *are reserved for use by the CBV standard, and this prefix may not be used to define vocabulary outside the CBV. New vocabulary elements outside the CBV standard are defined by using a private URI space as illustrated above, not by using* `urn:epcglobal:cbv:`.

17. EPCIS Event Details for Pedigree

This remainder of section defines individual EPCIS events for different steps in the pharmaceutical supply chain process for pedigree purposes. The EPCIS standard defines many fields of EPCIS events to be optional. In the context of a specific event defined in this guideline, a field that is optional in the EPCIS standard may be required to be present (or required to be omitted) for pedigree purposes. For clarity, the EPCIS event details tables throughout this section use the following notations to indicate what is required for pedigree purposes:

Required	The field is required in the context of this specific event. (This is always the case if the field is specified as required in the EPCIS standard.)
Optional	The field may or may not be included in the context of this specific event.
Conditional	In the context of this specific event, the field may be required, optional, or omitted depending on circumstances. The circumstances are specified in the description.
Omitted	The field is always omitted in the context of this specific event.

17.1.   Commissioning

Commissioning is the process of associating an object (e.g., bottle, case, tote, pallet, etc.) with an EPC (i.e., an identifier representing a GTIN / Serial Number, SSCC, etc.). The EPC may be encoded in a data carrier (i.e., a barcode or EPC/ RFID tag) and applied to the object during this step, or the data carrier may have been previously encoded.

❖ **A Commissioning event shall be an EPCIS Object Event populated as follows:**

Element	Usage	Type	Value	Reason
eventTime	Required	Timestamp	Date and time of event (see Section 14.1).	EPCIS standard definition
recordTime	Optional	Timestamp	(Optional) Date and time the event was recorded in an EPCIS repository.	EPCIS standard definition
eventTimeZoneOffset	Required	String	Time zone offset in effect at the time and place where the event occurred.	EPCIS standard definition
epcList	Required	List of URI	EPC(s) of the commissioned item in EPC Pure Identity URI format. If more than one EPC is included, they shall all have the same value for extensions defined below, or shall all require these extensions to be omitted. EPCs having different values for these extensions must be shared in different Commissioning events.	Because the extensions below are *event-level* extensions, they must be the same for all EPCs in the event.
action	Required	String	ADD	EPCIS standard definition
bizStep	Required	URI	urn:epcglobal:cbv:bizstep:commissioning	CBV standard definition
disposition	Required	URI	urn:epcglobal:cbv:disp:active	CBV standard definition: the *Disposition* value "active" is always used with the *Business Step* "commissioning."
readPoint	Optional	URI	EPC Pure Identity URI for the GLN of the location at which the event took place (see Section 14.2).	EPCIS standard definition
bizLocation	Required	URI	EPC Pure Identity URI for the GLN of the location where the objects are presumed to be following the event (see Section 14.2).	EPCIS standard definition
bizTransactionList	Omitted	List of biz transactions (each represented as a pair of URIs)		Omitted in Commissioning events as there are no relevant business transactions to share.

❖ Extensions used in Commissioning Events:

In addition to the EPCIS standard fields shown above, the following extensions are also included in a Commissioning event. (See Section 15 for general notes about extensions.)

Element	Usage	Type	Value
eventID	Optional	String	A universally unique identifier (UUID) as defined by IETF RFC 4122 that uniquely identifies this event, using the URN syntax also defined in RFC 4122. Currently this event ID is added here for the purposes of pilots to test the use and value of an ID for identifying and referencing EPCIS events (void, replace, etc.). *It is possible that this attribute will be adopted into the EPCIS standard and promoted to the standard set of attributes. At that time, this attribute will be removed from the extension as part of a future version of this guideline.*
additionalTradeItemIdentification	Conditional	AdditionalTradeIdentificationType (see below)	The product code associated with all of the EPCs in the epcList of the ObjectEvent.
tradeItemMasterData	Conditional	Complex Type tradeItemMasterData (see below)	Used for trading partners who do not employ a master data management strategy
lotNumber	Conditional (see notes below)	String	The lot or batch number for all of the EPCs in the epcList of the ObjectEvent.
itemExpirationDate	Conditional (see notes below)	Date	The expiration date for all of the EPCs in the epcList of the ObjectEvent, formatted as an xsd:date. *

* Special Notes:

The GS1 General Specification states that, for Expiration Date (AI 17) in a barcode, if only year and month are available, the day portion of the date must be filled with two zeroes (ex: January 2013 would be represented as "130100"). The itemExpirationDate attribute uses the W3C standard date format which does not allow "00" as a day. The GS1 US Secure Supply Chain Task Force is considering options to address this in an amendment to this guideline or in a future version. In the interim, certain manufacturers have elected to use the last day of the month in the itemExpirationDate attribute, please communicate to your trading partners how you plan on addressing this so that they can understand how to interpret the expiration date they receive in your barcoded product and EPCIS Commissioning events.

2011 HDMA Barcode Guidelines: *The application identifier for expiration date, AI(17), requires the "YYMMDD" (Year, Year, Month, Month, Day, Day) format. No other expiration date format is supported or allowed in the GS1 System. Yet some suppliers do not designate a day of the month as part of their expiration date. In this case "00" is used in the GS1 System as a place holder for the "DD" date segment when no day of the month is specified. The last day of the month is analogous to using 00 and is also perfectly acceptable. Whatever the human-readable format,HDMA recommends that the human-readable year always be represented in its complete "CCYY" (Century, Century, Year, Year) four-digit format.*

It also is important to note that the lack of a specified day of the month in the expiration date can cause confusion as to which day of the month is the expiration date. HDMA recognizes the following excerpt from the United States Pharmacopeia* (USP) as authoritative on the subject of the date format:

USP 34–NF 29 through Second Supplement 10.40.100. Expiration Date and Beyond-Use Date:

The label of an official drug product or nutritional or dietary supplement product shall bear an expiration date. The expiration date identifies the time during which the article may be expected to meet the requirements of the compendial monograph, provided it is kept under the prescribed storage conditions. The expiration date limits the time during which the article may be dispensed or used. Where an expiration date is stated only in terms of the month and the year, it is a representation that the intended expiration date is the last day of the stated month

* The USP is a non-governmental, official public standards-setting authority for prescription and over-the-counter medicines and other healthcare products manufactured or sold in the United States.

❖ The AdditionalTradeItemIdentificationType elements are:

Element	Usage	Type	Value
additionalTradeItemIdentificationValue	Required	String	The product code associated with all of the EPCs in the `epcList`.of the `ObjectEvent` For NDC, do not include dashes.
additionalTradeItemIdentificationType	Required	Additional TradeItem Identification ListType (enum list)	(Mandatory) The product code type. Valid values are: NDC442, NDC541, NDC532, NDC542

❖ The TradeItemMasterData elements are:

Element	Usage	Type	Value
drugName	Required	String	The name of the drug as it appears on the product label.
manufacturer	Required	String	The name of the manufacturer or repackager of the drug as it appears on the product label.
dosageForm	Required	String	Standard forms of drugs (AEROSOL, CAPSULE, GEL, PILL, TABLET) as defined by the FDA. The FDA currently defines 143 dosage forms.
strength	Required	String	The strength or potency of the product, including the unit of measure (for example, 60 mg, 25 ml).
containerSize	Required	String	The number of units contained in a package of the product (for example, 60, 100).This is also known as pack size.

❖ Commissioning ObjectEvent Rules:

- `ObjectEvents` for commissioning <u>item serial numbers</u> SHALL include the extension elements to define the product code, lot and expiration date.

- `ObjectEvents` for commissioning <u>homogenous containers</u> (e.g., cases and pallets of the same object) MAY include the extension elements to define the product code, lot and expiration date.

- `ObjectEvents` for commissioning <u>non-homogenous containers</u> (e.g., cases and pallets of different items, lots, etc.) SHALL NOT include the extension elements to define the product code, lot and expiration date.

- <u>All</u> of the EPCs within a single Commissioning event must belong to <u>only one</u> of the categories defined in the previous three rules Multiple Commissioning events must be used for EPCs belonging to different categories.

❖ Commissioning Event Example:

```xml
<epcis:EPCISDocument
    xmlns:gs1ushc="http://epcis.gs1us.org/hc/ns"
    xmlns:epcis="urn:epcglobal:epcis:xsd:1"
    schemaVersion="1.0"
    creationDate="2012-03-25T17:10:16Z">
  <EPCISBody>
    <EventList>
      <ObjectEvent>
        <eventTime>2012-03-25T17:10:16Z</eventTime>
        <eventTimeZoneOffset>-05:00</eventTimeZoneOffset>
        <epcList>
          <epc>urn:epc:id:sgtin:030001.0012345.10000000001</epc>
          <epc>urn:epc:id:sgtin:030001.0012345.10000000002</epc>
          <epc>urn:epc:id:sgtin:030001.0012345.10000000003</epc>
          <epc>urn:epc:id:sgtin:030001.1012345.22222222222</epc>
        </epcList>
        <action>ADD</action>
        <bizStep>urn:epcglobal:cbv:bizstep:commissioning</bizStep>
        <disposition>urn:epcglobal:cbv:disp:active</disposition>
        <readPoint>
          <id>urn:epc:id:sgln:030001.111111.0</id>
        </readPoint>
        <bizLocation>
          <id>urn:epc:id:sgln:030001.111111.0</id>
        </bizLocation>
         <gs1ushc:eventID>urn:uuid:f81d4fae-7dec-11d0-a765-00a0c91e6bf6</gs1ushc:eventID>


        <gs1ushc:additionalTradeItemIdentification>

<gs1ushc:additionalTradeItemIdentificationValue>0001012345</gs1ushc:additionalTradeItemIdentificationValue>

<gs1ushc:additionalTradeItemIdentificationType>NDC442</gs1ushc:additionalTradeItemIdentificationType>
        </gs1ushc:additionalTradeItemIdentification>
        <gs1ushc:tradeItemMasterData>
           <gs1ushc:drugName>Epcistra</gs1ushc:drugName>
           <gs1ushc:manufacturer>GS1 Pharma LLC</gs1ushc:manufacturer>
           <gs1ushc:dosageForm>PILL</gs1ushc:dosageForm>
           <gs1ushc:strength>100mg</gs1ushc:strength>
           <gs1ushc:containerSize>500</gs1ushc:containerSize>
        </gs1ushc:tradeItemMasterData>
        <gs1ushc:lotNumber>A123</gs1ushc:lotNumber>
        <gs1ushc:itemExpirationDate>2015-03-15</gs1ushc:itemExpirationDate>
      </ObjectEvent>
    </EventList>
  </EPCISBody>
</epcis:EPCISDocument>
```

17.2.   Packing

Packing denotes a specific activity within a business process that includes putting an object (e.g., individuals, inners, cases, pallets, etc.) into a larger container (e.g., cases, totes, pallets, etc.) usually for the purposes of storing or shipping. Aggregation of one unit to another occurs at this point.

❖ **A Packing event shall be an EPCIS Aggregation Event populated as follows:**

Element	Usage	Type	Value	Reason
eventTime	Required	Timestamp	Date and time of event (see Section 14.1).	EPCIS standard definition
recordTime	Optional	Timestamp	(Optional) Date and time the event was recorded in an EPCIS repository.	EPCIS standard definition
eventTimeZoneOffset	Required	String	Time zone offset in effect at the time and place where the event occurred.	EPCIS standard definition
parentID	Required	URI	EPC of the outer container in EPC Pure Identity URI format.	EPCIS standard definition
childEPCs	Required	List of URI	EPC(s) of the item(s) being packed into the parent in EPC Pure Identity URI format.	EPCIS standard definition
action	Required	String	ADD	EPCIS standard definition
bizStep	Required	URI	urn:epcglobal:cbv:bizstep:packing	CBV standard definition
disposition	Required	URI	urn:epcglobal:cbv:disp:in_progress	CBV standard definition
readPoint	Optional	URI	EPC Pure Identity URI for the GLN of the location at which the event took place (see Section 14.2).	EPCIS standard definition
bizLocation	Required	URI	EPC Pure Identity URI for the GLN of the location where the objects are presumed to be following the event (see Section 14.2).	EPCIS standard definition
bizTransactionList	Omitted	List of biz transactions (with each represented as a pair of URIs)		Omitted in the packing event as there are no relevant business transactions to share.

❖ Extensions used in Packing Events:

In addition to the EPCIS standard fields shown above, the following extensions are also included in a Packing event. (See Section 15 for general notes about extensions.)

Element	Usage	Type	Value
eventID	Optional	String	A universally unique identifier (UUID) as defined by IETF RFC 4122 that uniquely identifies this event, using the URN syntax also defined in RFC 4122. Currently this event ID is added here for the purposes of pilots to test the use and value of an ID for identifying and referencing EPCIS events (void, replace, etc.). *It is possible that this attribute will be adopted into the EPCIS standard and promoted to the standard set of attributes. At that time, this attribute will be removed from the extension as part of a future version of this guideline.*

❖ Packing Event Example:

```
<epcis:EPCISDocument
    xmlns:gs1ushc="http://epcis.gs1us.org/hc/ns"
    xmlns:epcis="urn:epcglobal:epcis:xsd:1"
    schemaVersion="1.0"
    creationDate="2012-03-25T17:10:16Z">
  <EPCISBody>
    <EventList>
      <AggregationEvent>
        <eventTime>2012-03-25T17:10:16Z</eventTime>
        <eventTimeZoneOffset>-05:00</eventTimeZoneOffset>
        <parentID>urn:epc:id:sgtin:030001.1012345.22222223333</parentID>
        <childEPCs>
          <epc>urn:epc:id:sgtin:030001.0012345.10000001001</epc>
          <epc>urn:epc:id:sgtin:030001.0012345.10000001002</epc>
          <epc>urn:epc:id:sgtin:030001.0012345.10000001003</epc>
        </childEPCs>
        <action>ADD</action>
        <bizStep>urn:epcglobal:cbv:bizstep:packing</bizStep>
        <disposition>urn:epcglobal:cbv:disp:in_progress</disposition>
        <readPoint>
          <id>urn:epc:id:sgln:030001.111111.0</id>
        </readPoint>
        <bizLocation>
          <id>urn:epc:id:sgln:030001.111111.0</id>
        </bizLocation>
        <gs1ushc:eventID>urn:uuid:f81d4fae-7dec-11d0-a765-00a0c91e6bf6</gs1ushc:eventID>
      </AggregationEvent>
    </EventList>
  </EPCISBody>
</epcis:EPCISDocument>
```

17.3. Shipping

Shipping is the process of initiating the transfer an object from one trading partner to another. A data carrier (i.e., a bar code or EPC/RFID tag) may have been read during this process.   Only the outermost containers in the packaging hierarchy are included.

❖ **A Shipping event shall be an EPCIS Object Event populated as follows:**

Element	Usage	Type	Value	Reason
eventTime	Required	Timestamp	Date and time of event (see Section 14.1).	EPCIS standard definition
recordTime	Optional	Timestamp	Date and time the event was recorded in an EPCIS repository.	EPCIS standard definition
eventTimeZoneOffset	Required	String	Time zone offset in effect at the time and place where the event occurred.	EPCIS standard definition
epcList	Required	List of URI	EPC(s) of the shipped item(s) in EPC Pure Identity URI format. Only the outermost containers in the packaging hierarchy are included.	For pedigree purposes, the Shipping event only needs the outermost identifiers because separate Packing events are used to indicate the hierarchy.
action	Required	String	OBSERVE	EPCIS standard definition
bizStep	Required	URI	urn:epcglobal:cbv:bizstep:shipping	CBV standard definition
disposition	Required	URI	urn:epcglobal:cbv:disp:in_transit	CBV standard definition. The *Disposition* value "in_transit" is always paired with the *Business Step* "shipping" for forward logistics.
readPoint	Optional	URI	EPC Pure Identity URI for the GLN of the location at which the event took place (see Section 14.2).	EPCIS standard definition
bizLocation	Optional	URI		The *Business Location* is the location where the objects are presumed to be following the event. For a Shipping event, this is unknown until a Receiving event occurs. Therefore, *Business Location* is always omitted for a Shipping event. (Note that extension elements in this event provide *"Ship from"* and *"Ship to"* information.
bizTransactionList	Optional	List of biz transactions (each represented as a pair of URIs)	Business transactions governing this Shipping event, which may include a purchase order or an invoice (see Section 14.3 for details).	Optional from an EPCIS standard perspective, however, certain regulations and business agreements may require the use for P.O., Invoice or other ID's.

❖ Extensions used in Shipping Events

In addition to the EPCIS standard fields listed above, the following extensions are also included in a Shipping event. (See Section 15 for general notes about extensions.)

Element	Usage	Type	Value
eventID	Optional	String	A universally unique identifier (UUID) as defined by IETF RFC 4122 that uniquely identifies this event, using the URN syntax also defined in RFC 4122. Currently this event ID is added here for the purposes of pilots to test the use and value of an ID for identifying and referencing EPCIS events (void, replace, etc.). *It is possible that this attribute will be adopted into the EPCIS standard and promoted to the standard set of attributes. At that time, this attribute will be removed from the extension as part of a future version of this guideline.*
transferredById	Required	String	The identifier of the party that transferred the goods (in the format implied by the accompanying `@type` attribute)
@type	Required	PartyIdQualifierEnum (enum list)	*(See the list of values in the sections following this table.)*
shipFromLocationId	Conditional	String	The identifier of the location where the goods are shipped from (in the format implied by the accompanying `@type` attribute). Only included if different from transferredById.
@type	Conditional	PartyIdQualifierEnum (enum list)	*(See the list of values in the sections following this table.)*
shipFromLocationAddress	Optional	AddressType	Fully enumerated address.
transferredToId	Required	String	The identifier of the party that the goods were transferred to (in the format implied by the accompanying `@type` attribute). Indicates the change of ownership. Previous owner (transferredByID) has transferred ownership to this party.
@type	Required	PartyIdQualifierEnum (enum list)	*(See the list of values in the sections following this table.)*
shipToLocationId	Conditional	String	The identifier of the location where the goods were shipped to (in the format implied by the accompanying `@type` attribute). Only included if different from transferredToId.
@type	Conditional	PartyIdQualifierEnum (enum list)	*(See the list of values in the sections following this table.)*
shipToLocationAddress	Optional	AddressType	Fully enumerated address.

Element	Usage	Type	Value
shipFromLicenseList	Conditional	List of LicenseListType. Multiple LicenseListType instances may be included to express as many licenses as needed.	(Mandatory for compliance with CA, but may not be needed in other states.) A list of one or more state or federal license numbers for the party that sold the goods. *(See the list of values in the sections following this table.)*
shipToLicenseList	Conditional	List of LicenseListType. Multiple LicenseListType instances may be included to express as many licenses as needed.	(Mandatory for compliance with CA, but may not be needed in other states.) A list of one or more state or federal license numbers for the party that the goods were shipped to. *(See the list of values in the sections following this table.)*
soldFromContact	Optional	ContactType	Contact information for the seller

❖ The PartyIdQualifierEnum code list values are:

GLN	GS1 GLN for the company, expressed as a 13-digit string
SGLN	GS1 GLN for the facility, expressed in SGLN EPC Pure Identity URI format, ending in ".0" to indicate the lack of a GLN extension. (See Sections 6.3.3 and 7.3 of the EPC Tag Data Standard.)
DEA	Drug Enforcement Agency Number
HIN	HIBCC Health Industry Number

ⓘ *GS1 Healthcare US recommends the use of GLN and/or SGLN as they maintain alignment with the GS1 System of Standards. GS1 Healthcare US discourages the use of identifiers from outside the GS1 System because they may not be global, and/or because issuing agencies for some identifiers do not approve of the use of their identifiers beyond the specific application for which they were issued.*

❖ The AddressType elements are:

Element	Usage	Type	Value
street1	Required	String	The first line of the street address.
street2	Optional	String	The second line of the street address.
city	Required	String	The city.
stateOrRegion	Required	String	The state, province, or region using the standard two-letter abbreviation specified in ISO 3166-2:1998 country subdivision code [16].
postalCode	Required	String	The ZIP or other postal code.
country	Required	String	The country using the standard two-letter abbreviation specified in ISO 3166-1alpha-2:1997 country code [17].

❖ **The** `LicenseListType` **elements are:**

Element	Usage	Type	Value
licenseNumber	Required	String	A list of one or more state or federal license numbers for the trading partner.
@state	Optional	String	The state or region in which the trading partner is licensed, using the standard two letter abbreviation specified in ISO 3166-2:1998 country sub-division code. This attribute is used to give additional context to the license number.
@agency	Optional	String	The agency that granted the license (e.g., Florida DOH, NABP). This attribute is used to give additional context to the license number.

❖ **The** `ContactType` **elements are:**

Element	Usage	Type	Value
name	Optional	String	The name of the contact department or individual at the company.
title	Optional	String	The title of the individual.
telephone	Optional	String	The phone number of the contact department or individual at the company. This SHALL begin with the "+" character followed by the Country Calling Code.
email	Optional	String	The email address of the contact department or individual at the company.
url	Optional	String	The Web address to facilitate authentication.

❖ Shipping Event Example:

```xml
<epcis:EPCISDocument
   xmlns:gs1ushc="http://epcis.gs1us.org/hc/ns"
   xmlns:epcis="urn:epcglobal:epcis:xsd:1"
   schemaVersion="1.0"
   creationDate="2012-03-25T17:10:16Z">
  <EPCISBody>
    <EventList>
      <ObjectEvent>
        <eventTime>2012-03-25T17:10:16Z</eventTime>
        <eventTimeZoneOffset>-05:00</eventTimeZoneOffset>
        <epcList>
          <epc>urn:epc:id:sscc:030001.01234567890</epc>
        </epcList>
        <action>OBSERVE</action>
        <bizStep>urn:epcglobal:cbv:bizstep:shipping</bizStep>
        <disposition>urn:epcglobal:cbv:disp:in_transit</disposition>
        <readPoint>
          <id>urn:epc:id:sgln:030001.111111.0</id>
        </readPoint>
        <bizTransactionList>
          <bizTransaction
type="urn:epcglobal:cbv:btt:inv">urn:epcglobal:cbv:bt:0300011111116:A123</bizTransaction>
          <bizTransaction type="urn:epcglobal:cbv:btt:po">urn:epcglobal:cbv:bt:
0399999999991:XYZ567</bizTransaction>
        </bizTransactionList>
        <gs1ushc:eventID>urn:uuid:f81d4fae-7dec-11d0-a765-00a0c91e6bf6</gs1ushc:eventID>
        <gs1ushc:transferredById type="GLN">0300011111116</gs1ushc:transferredById>
        <gs1ushc:shipFromLocationId type="GLN">0300011111116</gs1ushc:shipFromLocationId>
        <gs1ushc:shipFromLocationAddress>
          <gs1ushc:street1>1295 S George Ave</gs1ushc:street1>
          <gs1ushc:street2>Room 378</gs1ushc:street2>
          <gs1ushc:city>Washington</gs1ushc:city>
          <gs1ushc:stateOrRegion>DC</gs1ushc:stateOrRegion>
          <gs1ushc:postalCode>12345-6789</gs1ushc:postalCode>
          <gs1ushc:country>US</gs1ushc:country>
        </gs1ushc:shipFromLocationAddress>
        <gs1ushc:transferredToId type="GLN">0399999999991</gs1ushc:transferredToId>
        <gs1ushc:shipToLocationId type="GLN">0399999999991</gs1ushc:shipToLocationId>
        <gs1ushc:shipToLocationAddress>
          <gs1ushc:street1>230 Park Ave S</gs1ushc:street1>
          <gs1ushc:city>New York</gs1ushc:city>
          <gs1ushc:stateOrRegion>NY</gs1ushc:stateOrRegion>
          <gs1ushc:postalCode>10003-1502</gs1ushc:postalCode>
          <gs1ushc:country>US</gs1ushc:country>
        </gs1ushc:shipToLocationAddress>
        <gs1ushc:shipFromLicenseList>
          <gs1ushc:licenseNumber state="TN" agency="SLN">0000001013</gs1ushc:licenseNumber>
        </gs1ushc:shipFromLicenseList>
        <gs1ushc:soldFromContact>
          <gs1ushc:name>CONTACT NAME</gs1ushc:name>
          <gs1ushc:telephone>+1-212-555-5624</gs1ushc:telephone>
          <gs1ushc:email>contact.name@example.com</gs1ushc:email>
        </gs1ushc:soldFromContact>
      </ObjectEvent>
    </EventList>
  </EPCISBody>
</epcis:EPCISDocument>
```

17.4.   Receiving

Receiving is the process of completing the transfer of an object from one trading partner to another. Receiving may be recorded in one of two ways:

1: Only the outermost containers in the packaging hierarchy are included in the Receiving event, in which case the full hierarchy inferred from prior Packing events is inferred to have been received, <u>or</u>

2: One or more inner levels of hierarchy are declared explicitly in one or more Receiving events, in which case inference is only used for inner levels not declared explicitly (or not at all if all levels are declared explicitly)

If the Receiving event is to be recorded using the first method (i.e., where only the outermost containers are included in the Receiving event), the Receiving event shall be an EPCIS <u>Object Event</u> populated as specified below. If the Receiving event is to be recorded using the second method (i.e., where hierarchy is declared explicitly), share as many Receiving Events as needed to express the hierarchy. Each event shall be an EPCIS <u>Aggregation Event</u> where the *Parent ID* and *Child EPC List* fields express the hierarchy and all other fields (including the action and the extensions) are as specified below.

Element	Usage	Type	Value	Reason
eventTime	Required	Timestamp	Date and time of event (see Section 14.1).	EPCIS standard definition
recordTime	Optional	Timestamp	Date and time the event was recorded in an EPCIS repository.	EPCIS standard definition
eventTimeZoneOffset	Required	String	Time zone offset in effect at the time and place where the event occurred.	EPCIS standard definition
epcList	Required	List of URI	EPC(s) of the received item(s) in EPC Pure Identity URI format. *If an *Object Event* is used, only the outermost containers in the packaging hierarchy are included. * If *Aggregation Events* are used, the event contains parentID and childEPCs fields (instead of the epcList field) for expressing the observed hierarchy.	See the discussion above regarding receiving options.
action	Required	String	OBSERVE	EPCIS standard definition
bizStep	Required	URI	urn:epcglobal:cbv:bizstep:receiving	CBV standard definition
disposition	Required	URI	urn:epcglobal:cbv:disp:in_progress	CBV standard definition
readPoint	Optional	URI	EPC Pure Identity URI for the GLN of the location at which the event took place. (See Section 14.2.)	EPCIS standard definition
bizLocation	Required	URI	EPC Pure Identity URI for the GLN of the location where the objects are presumed to be following the event. (See Section 14.2.)	EPCIS standard definition
bizTransactionList	Optional	List of biz transactions, (each represented as a pair of URIs)	Business transactions governing this shipping event, which may include a purchase order or an invoice. (See Section 14.3 for details.)	Optional from an EPCIS standard perspective, however, certain regulations and business agreements may require the use for P.O., Invoice or other ID's.

❖ Extensions used in Receiving Events

In addition to the EPCIS standard fields, the following extensions are included in a Receiving event. (See Section 15 for general notes about extensions.)

Element	Usage	Type	Value
eventID	Optional	String	A universally unique identifier (UUID) as defined by IETF RFC 4122 that uniquely identifies this event, using the URN syntax also defined in RFC 4122. Currently this event ID is added here for the purposes of pilots to test the use and value of an ID for identifying and referencing EPCIS events (void, replace, etc.). *It is possible that this attribute will be adopted into the EPCIS standard and promoted to the standard set of attributes. At that time, this attribute will be removed from the extension as part of a future version of this guideline.*
transferredById	Required	String	The identifier of the party that transferred the goods (in the format implied by the accompanying `@type` attribute)
@type	Required	PartyIdQualifierEnum (enum list)	*(See the list of values in the section following this table.)*
transferredToId	Required	String	The identifier of the party that the goods were transferred to (in the format implied by the accompanying `@type` attribute). Indicates the change of ownership. Previous owner (transferredByID) has transferred ownership to this party.
@type	Required	PartyIdQualifierEnum (enum list)	*(See the list of values in the sections following this table.)*
shipToLocationId	Conditional	String	The identifier of the location where the goods where shipped to, in the format implied by the accompanying `@type` attribute. Only included if different from transferredToId
@type	Conditional	PartyIdQualifierEnum (enum list)	*(See the list of values in the sections following this table.)*
shipToLocationAddress	Optional	AddressType	Fully enumerated address.
receivedByContact	Optional	ContactType (see Section 13)	Contact information for the receiver

Best Practice:

▪ To help in later matching Shipping and Receiving events, if possible, use the same values found in your trading partner's "Shipping" event for transferredByID and transferredToID in your "Receiving" event.

❖ The PartyIdQualifierEnum code list values are:

GLN	GS1 GLN for the company, expressed as a 13-digit string
SGLN	GS1 GLN for the facility, expressed in SGLN EPC Pure Identity URI format, ending in ".0" to indicate the lack of a GLN extension. (See Sections 6.3.3 and 7.3 of the EPC Tag Data Standard.)
DEA	Drug Enforcement Agency Number
HIN	HIBCC Health Industry Number

ⓘ *GS1 Healthcare US recommends the use of GLN and/or SGLN as they maintain alignment with the GS1 System of Standards. GS1 Healthcare US discourages the use of identifiers from outside the GS1 System because they may not be global, and/or because issuing agencies for some identifiers do not approve of the use of their identifiers beyond the specific application for which they were issued.*

❖ The AddressType elements are:

Element	R/O	Type	Value
street1	Required	String	The first line of the street address.
street2	Optional	String	The second line of the street address.
city	Required	String	The city.
stateOrRegion	Required	String	The state, province, or region using the standard two-letter abbreviation specified in ISO 3166-2:1998 country subdivision code [16].
postalCode	Required	String	The ZIP or other postal code.
country	Required	String	The country using the standard two-letter abbreviation specified in ISO 3166-1alpha-2:1997 country code [17].

❖ Receiving Event Example:

```xml
<epcis:EPCISDocument
   xmlns:gs1ushc="http://epcis.gs1us.org/hc/ns"
   xmlns:epcis="urn:epcglobal:epcis:xsd:1"
   schemaVersion="1.0"
   creationDate="2012-03-25T17:10:16Z">
  <EPCISBody>
    <EventList>
      <ObjectEvent>
        <eventTime>2012-03-25T17:10:16Z</eventTime>
        <eventTimeZoneOffset>-05:00</eventTimeZoneOffset>
        <epcList>
          <epc>urn:epc:id:sscc:030001.01234567890</epc>
        </epcList>
        <action>OBSERVE</action>
        <bizStep>urn:epcglobal:cbv:bizstep:receiving</bizStep>
        <disposition>urn:epcglobal:cbv:disp:in_progress</disposition>
        <readPoint>
          <id>urn:epc:id:sgln:039999.999999.0</id>
        </readPoint>
        <bizLocation>
          <id>urn:epc:id:sgln:039999.999999.0</id>
        </bizLocation>
        <bizTransactionList>
          <bizTransaction
type="urn:epcglobal:cbv:btt:inv">urn:epcglobal:cbv:bt:0300011111116:A123</bizTransaction>
          <bizTransaction type="urn:epcglobal:cbv:btt:po">urn:epcglobal:cbv:bt:
0399999999991:XYZ567</bizTransaction>
        </bizTransactionList>
        <gs1ushc:eventID>urn:uuid:f81d4fae-7dec-11d0-a765-00a0c91e6bf6</gs1ushc:eventID>
        <gs1ushc:transferredById type="GLN">0300011111116</gs1ushc:transferredById>
        <gs1ushc:transferredToId type="GLN">0399999999991</gs1ushc:transferredToId>
        <gs1ushc:shipToLocationId type="GLN">0399999999991</gs1ushc:shipToLocationId>
        <gs1ushc:shipToLocationAddress>
          <gs1ushc:street1>230 Park Ave S</gs1ushc:street1>
          <gs1ushc:city>New York</gs1ushc:city>
          <gs1ushc:stateOrRegion>NY</gs1ushc:stateOrRegion>
          <gs1ushc:postalCode>10003-1502</gs1ushc:postalCode>
          <gs1ushc:country>US</gs1ushc:country>
        </gs1ushc:shipToLocationAddress>
        <gs1ushc:receivedByContact>
          <gs1ushc:name>CONTACT NAME</gs1ushc:name>
          <gs1ushc:telephone>+1-212-555-5624</gs1ushc:telephone>
          <gs1ushc:email>contact.name@example.com</gs1ushc:email>
        </gs1ushc:receivedByContact>
      </ObjectEvent>
    </EventList>
  </EPCISBody>
</epcis:EPCISDocument>
```

17.5.   Unpacking

Unpacking denotes a specific activity within a business process that includes removing an object (e.g., individuals, inners, cases, pallets, etc.) from a larger container (e.g., cases, totes, pallets, etc.) – usually for the purposes of storing or shipping. Unpacking is the reverse of Packing, and the Unpacking EPCIS event disaggregates specific aggregation relationships created by Packing events.

❖ **An Unpacking event shall be an EPCIS Aggregation Event populated as follows:**

Element	Usage	Type	Value	Reason
eventTime	Required	Timestamp	Date and time of event. (See Section 14.)	EPCIS standard definition
recordTime	Optional	Timestamp	(Optional) Date and time the event was recorded in an EPCIS repository.	EPCIS standard definition
eventTimeZoneOffset	Required	String	Time zone offset in effect at the time and place where the event occurred.	EPCIS standard definition
parentID	Required	URI	EPC of the outer container in EPC Pure Identity URI format	EPCIS standard definition
childEPCs	Required	List of URI	EPC(s) of the item(s) unpacked from the parent in EPC Pure Identity URI format	EPCIS standard definition. [Although the EPCIS standard permits childEPCs to be omitted to indicate that all children are disaggregated from the parent, this usage is <u>not</u> permitted for this guideline.)
action	Required	String	DELETE	EPCIS standard definition
bizStep	Required	URI	http://epcis.gs1us.org/hc/bizstep/unpacking	Extension vocabulary element introduced in this guideline
disposition	Required	URI	urn:epcglobal:cbv:disp:in_progress	CBV standard definition
readPoint	Optional	URI	EPC Pure Identity URI for the GLN of the location at which the event took place. (See Section 14.2.)	EPCIS standard definition
bizLocation	Required	URI	EPC Pure Identity URI for the GLN of the location where the objects are presumed to be following the event. (See Section 14.2.)	EPCIS standard definition
bizTransactionList	Omitted	List of biz transactions (each represented as a pair of URIs)		Omitted in the packing event as there are no relevant business transactions to share

❖ Extensions used in Unpacking Events

In addition to the EPCIS standard fields, the following extensions are included in an Unpacking event. (See Section 15 for general notes about extensions.)

Element	Usage	Type	Value
eventID	Optional	String	A universally unique identifier (UUID) as defined by IETF RFC 4122 that uniquely identifies this event, using the URN syntax also defined in RFC 4122. Currently this event ID is added here for the purposes of pilots to test the use and value of an ID for identifying and referencing EPCIS events (void, replace, etc.). *It is possible that this attribute will be adopted into the EPCIS standard and promoted to the standard set of attributes. At that time, this attribute will be removed from the extension as part of a future version of this guideline.*

❖ Unpacking Event Example:

```
<epcis:EPCISDocument
   xmlns:gs1ushc="http://epcis.gs1us.org/hc/ns"
   xmlns:epcis="urn:epcglobal:epcis:xsd:1"
   schemaVersion="1.0"
   creationDate="2012-03-25T17:10:16Z">
 <EPCISBody>
   <EventList>
     <AggregationEvent>
       <eventTime>2012-03-25T17:10:16Z</eventTime>
       <eventTimeZoneOffset>-05:00</eventTimeZoneOffset>
       <parentID>urn:epc:id:sgtin:030001.1012345.22222223333</parentID>
       <childEPCs>
         <epc>urn:epc:id:sgtin:030001.0012345.10000001001</epc>
         <epc>urn:epc:id:sgtin:030001.0012345.10000001002</epc>
       </childEPCs>
       <action>DELETE</action>
       <bizStep>http://epcis.gs1us.org/hc/bizstep/unpacking</bizStep>
       <disposition>urn:epcglobal:cbv:disp:in_progress</disposition>
       <readPoint>
         <id>urn:epc:id:sgln:039999.999999.0</id>
       </readPoint>
       <bizLocation>
         <id>urn:epc:id:sgln:039999.999999.0</id>
       </bizLocation>
       <gs1ushc:eventID>urn:uuid:f81d4fae-7dec-11d0-a765-00a0c91e6bf6</gs1ushc:eventID>
     </AggregationEvent>
   </EventList>
 </EPCISBody>
</epcis:EPCISDocument>
```

17.6.   End of Useful Life EPCIS Events

The following EPCIS events represent business processes that occur at the end of the supply chain, typically at a hospital or pharmacy.

17.6.1.   Dispensing

Dispensing is the process of removing a portion of a product for use while retaining the remainder for subsequent dispensing, such as when individual tablets are removed from a bottle to fill a prescription. The EPCIS event indicates the item from which the portion was dispensed. Unlike destroying or decommissioning, the item continues to exist after dispensing, but a special disposition value is used to indicate that the item is no longer in its original state. After all portions have been dispensed from an item, it is subsequently destroyed.

❖ **A Dispensing event shall be an EPCIS Object Event populated as follows:**

Element	Usage	Type	Value	Reason
eventTime	Required	Timestamp	Date and time of event. (See Section 14.)	EPCIS standard definition
recordTime	Optional	Timestamp	(Optional) Date and time the event was recorded in an EPCIS repository.	EPCIS standard definition
eventTimeZoneOffset	Required	String	Time zone offset in effect at the time and place where the event occurred.	EPCIS standard definition
epcList	Required	List of URI	EPC of the dispensed item in EPC Pure Identity URI format.	EPCIS standard definition
action	Required	String	OBSERVE	EPCIS standard definition
bizStep	Required	URI	http://epcis.gs1us.org/hc/bizstep/dispensing	Extension vocabulary element introduced in this guideline
disposition	Required	URI	http://epcis.gs1us.org/hc/disp/partial	Extension vocabulary element introduced in this guideline. "Partial" denotes that the item being dispensed from is no longer the same as originally packaged.
readPoint	Optional	URI	EPC Pure Identity URI for the GLN of the location at which the event took place. (See Section 14.2.)	EPCIS standard definition
bizLocation	Required	URI	EPC Pure Identity URI for the GLN of the location where the objects are presumed to be following the event. (See Section 14.2.)	EPCIS standard definition
bizTransactionList	Optional	List of biz transactions (each represented as a pair of URIs)		*The pharmacy could choose to insert the prescription ID if they wanted to extend traceability to the patient. (There may already be this type of function in the pharmacy system).*

❖ Extensions used in Dispensing Events

In addition to the EPCIS standard fields, the following extensions are included in a Dispensing event. (See Section 15 for general notes about extensions.)

Element	Usage	Type	Value
eventID	Optional	String	A universally unique identifier (UUID) as defined by IETF RFC 4122 that uniquely identifies this event, using the URN syntax also defined in RFC 4122. Currently this event ID is added here for the purposes of pilots to test the use and value of an ID for identifying and referencing EPCIS events (void, replace, etc.). *It is possible that this attribute will be adopted into the EPCIS standard and promoted to the standard set of attributes. At that time, this attribute will be removed from the extension as part of a future version of this guideline.*

❖ Dispensing Event Example:

```
<epcis:EPCISDocument
   xmlns:gs1ushc="http://epcis.gs1us.org/hc/ns"
   xmlns:epcis="urn:epcglobal:epcis:xsd:1"
   schemaVersion="1.0"
   creationDate="2012-03-25T17:10:16Z">
  <EPCISBody>
    <EventList>
      <ObjectEvent>
        <eventTime>2012-03-25T17:10:16Z</eventTime>
        <eventTimeZoneOffset>-05:00</eventTimeZoneOffset>
        <epcList>
          <epc>urn:epc:id:sgtin:030001.0012345.10000000001</epc>
        </epcList>
        <action>OBSERVE</action>
        <bizStep>http://epcis.gs1us.org/hc/bizstep/dispensing</bizStep>
        <disposition>http://epcis.gs1us.org/hc/disp/partial</disposition>
        <readPoint>
          <id>urn:epc:id:sgln:039999.111111.0</id>
        </readPoint>
        <bizLocation>
          <id>urn:epc:id:sgln:039999.111111.0</id>
        </bizLocation>
        <gs1ushc:eventID>urn:uuid:f81d4fae-7dec-11d0-a765-00a0c91e6bf6</gs1ushc:eventID>
      </ObjectEvent>
    </EventList>
  </EPCISBody>
</epcis:EPCISDocument>
```

17.6.2. Destroying

Destroying is the process of destroying a product so that it no longer exists, as opposed to decommissioning which implies that the item may still exist even though it no longer carries serialized identification. Destroying occurs when a party at the end of the supply chain physically destroys a product.

❖ **A Destroying event shall be an EPCIS Object Event populated as follows:**

Element	Usage	Type	Value	Reason
eventTime	Required	Timestamp	Date and time of event. (See Section 14.1.)	EPCIS standard definition
recordTime	Optional	Timestamp	(Optional) Date and time the event was recorded in an EPCIS repository.	EPCIS standard definition
eventTimeZoneOffset	Required	String	Time zone offset in effect at the time and place where the event occurred.	EPCIS standard definition
epcList	Required	List of URI	EPC(s) of the destroyed item(s) in EPC Pure Identity URI format	EPCIS standard definition
action	Required	String	DELETE	EPCIS standard definition. (Action DELETE in an Object Event indicates that the EPCs no longer exist.)
bizStep	Required	URI	urn:epcglobal:cbv:bizstep:destroying	CBV standard definition
disposition	Required	URI	urn:epcglobal:cbv:disp:destroyed	CBV standard definition
readPoint	Optional	URI	EPC Pure Identity URI for the GLN of the location at which the event took place. (See Section 14.2.)	EPCIS standard definition
bizLocation	Omitted	URI		The Business Location is the location where the object is presumed to be following the event. For a Destroying event, the object no longer exists following the event. Therefore, Business Location is always omitted for a Destroying event.
bizTransactionList	Omitted	List of biz transactions (each represented as a pair of URIs)		Omitted in the Destroying event as there are no relevant business transactions to share.

❖ Extensions used in Destroying Events

In addition to the EPCIS standard fields, the following extensions are included in a Destroying event. (See Section 15 for general notes about extensions.)

Element	Usage	Type	Value
eventID	Optional	String	A universally unique identifier (UUID) as defined by IETF RFC 4122 that uniquely identifies this event, using the URN syntax also defined in RFC 4122. Currently this event ID is added here for the purposes of pilots to test the use and value of an ID for identifying and referencing EPCIS events (void, replace, etc.). *It is possible that this attribute will be adopted into the EPCIS standard and promoted to the standard set of attributes. At that time, this attribute will be removed from the extension as part of a future version of this guideline.*

❖ Destroying Event Example:

```
<epcis:EPCISDocument
    xmlns:gs1ushc="http://epcis.gs1us.org/hc/ns"
    xmlns:epcis="urn:epcglobal:epcis:xsd:1"
    schemaVersion="1.0"
    creationDate="2012-03-25T17:10:16Z">
  <EPCISBody>
    <EventList>
      <ObjectEvent>
        <eventTime>2012-03-25T17:10:16Z</eventTime>
        <eventTimeZoneOffset>-05:00</eventTimeZoneOffset>
        <epcList>
          <epc>urn:epc:id:sgtin:030001.0012345.10000000001</epc>
        </epcList>
        <action>DELETE</action>
        <bizStep>urn:epcglobal:cbv:bizstep:destroying</bizStep>
        <disposition>urn:epcglobal:cbv:disp:destroyed</disposition>
        <readPoint>
          <id>urn:epc:id:sgln:039999.111111.0</id>
        </readPoint>
        <gs1ushc:eventID>urn:uuid:f81d4fae-7dec-11d0-a765-00a0c91e6bf6</gs1ushc:eventID>
      </ObjectEvent>
    </EventList>
  </EPCISBody>
</epcis:EPCISDocument>
```

17.6.3. Decommissioning

Decommissioning is the process of removing the EPC from the item so that it is no longer tracked. Unlike the Destroying business process, the item may still physically exist after decommissioning even though it no longer carries serialized identification. Decommissioning occurs when a party at the end of the supply chain removes the serialized identification (i.e., at point of sale.

❖ **A Decommissioning event shall be an EPCIS Object Event populated as follows:**

Element	Usage	Type	Value	Reason
eventTime	Required	Timestamp	Date and time of event. See Section 14.1.	EPCIS standard definition
recordTime	Optional	Timestamp	(Optional) Date and time the event was recorded in an EPCIS repository.	EPCIS standard definition
eventTimeZoneOffset	Required	String	Time zone offset in effect at the at the time and place where the event occurred.	EPCIS standard definition
epcList	Required	List of URI	EPC(s) of the decommissioned item(s) (EPC Pure Identity URI format)	EPCIS standard definition
action	Required	String	DELETE	EPCIS standard definition. Action DELETE in an Object Event indicates that the EPCs no longer exist
bizStep	Required	URI	urn:epcglobal:cbv:bizstep:decommissioning	CBV standard definition
disposition	Required	URI	urn:epcglobal:cbv:disp:inactive	CBV standard definition
readPoint	Optional	URI	EPC Pure Identity URI for the GLN of the location at which the event took place. (See Section 14.2.)	EPCIS standard definition
bizLocation	Omitted	URI		The Business Location is the location where the objects are presumed to be following the event. For a decommissioning event, the location of objects can no longer be tracked following the event and so Business Location is always omitted for a Decommissioning event.
bizTransactionList	Omitted	List of biz transactions, each a pair of URIs		Omitted in the Decommissioning event as there are no relevant business transactions to share

❖ Extensions used in Decommissioning Events

In addition to the EPCIS standard fields, the following extensions are included in a Decommissioning event. (See Section 15 for general notes about extensions.)

Element	Usage	Type	Value
eventID	Optional	String	A universally unique identifier (UUID) as defined by IETF RFC 4122 that uniquely identifies this event, using the URN syntax also defined in RFC 4122. Currently this event ID is added here for the purposes of pilots to test the use and value of an ID for identifying and referencing EPCIS events (void, replace, etc.). *It is possible that this attribute will be adopted into the EPCIS standard and promoted to the standard set of attributes. At that time, this attribute will be removed from the extension as part of a future version of this guideline.*

❖ Decommissioning Event Example:

```
<epcis:EPCISDocument
    xmlns:gs1ushc="http://epcis.gs1us.org/hc/ns"
    xmlns:epcis="urn:epcglobal:epcis:xsd:1"
    schemaVersion="1.0"
    creationDate="2012-03-25T17:10:16Z">
  <EPCISBody>
    <EventList>
      <ObjectEvent>
        <eventTime>2012-03-25T17:10:16Z</eventTime>
        <eventTimeZoneOffset>-05:00</eventTimeZoneOffset>
        <epcList>
          <epc>urn:epc:id:sgtin:030001.0012345.10000000001</epc>
        </epcList>
        <action>DELETE</action>
        <bizStep>urn:epcglobal:cbv:bizstep:decommissioning</bizStep>
        <disposition>urn:epcglobal:cbv:disp:inactive</disposition>
        <readPoint>
          <id>urn:epc:id:sgln:039999.111111.0</id>
        </readPoint>
        <gs1ushc:eventID>urn:uuid:f81d4fae-7dec-11d0-a765-00a0c91e6bf6</gs1ushc:eventID>
      </ObjectEvent>
    </EventList>
  </EPCISBody>
</epcis:EPCISDocument>
```

Part 6: Sample Supply Chain Event Choreographies for Pedigree

18. Model & Key for EPCIS Event Choreographies

In order to understand and hold conversations about EPCIS events supporting pedigree or other processes, it is helpful to use diagrams to show the choreography (or full set of events) that take place among a given set of trading partners. The following diagram was developed as the model to use for depicting the choreography of messages between trading partners in a specific scenario.
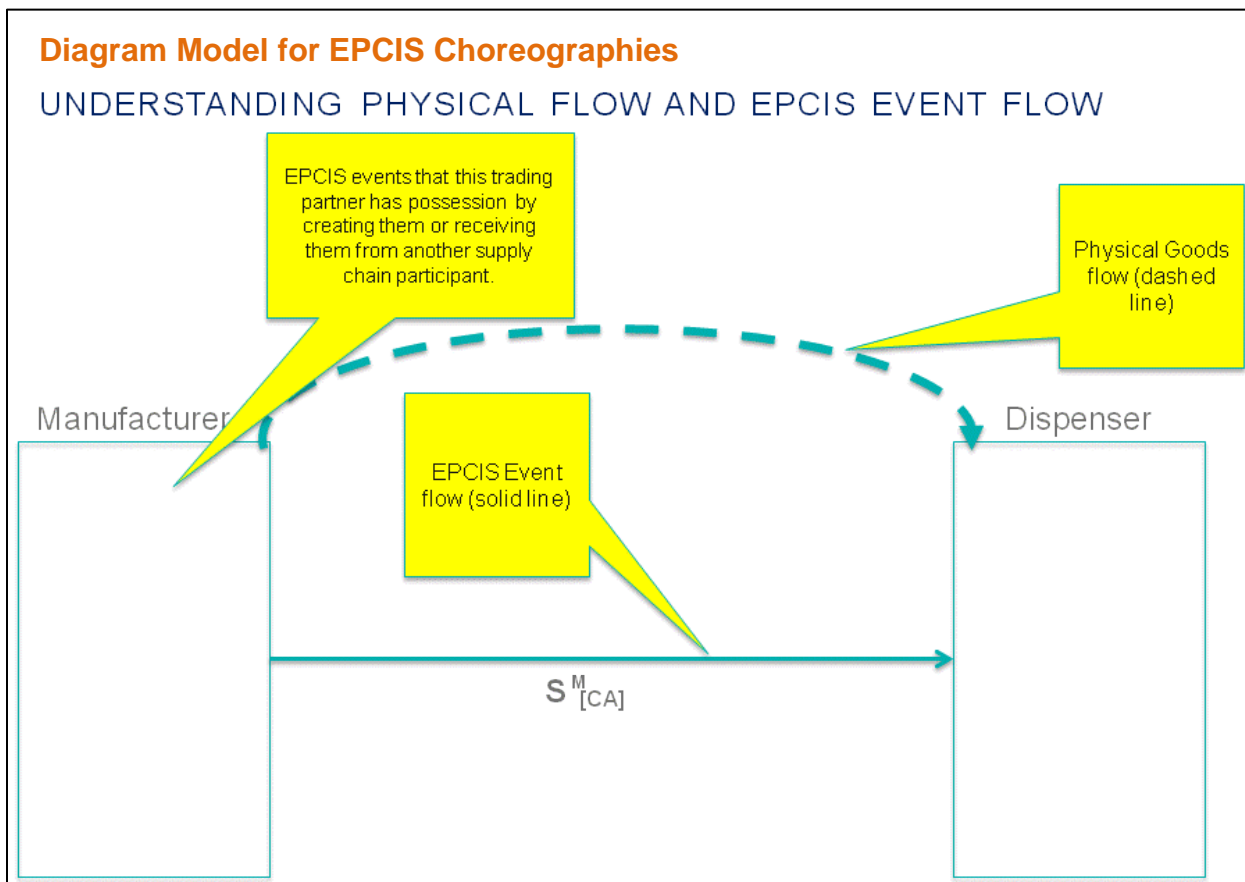
Figure 17: Model for EPCIS Choreography Diagrams

The diagram model shows the trading partners involved in the scenario, the physical flow of product (dashed line), and the EPCIS events transacted in the scenario (solid line). The EPCIS events within each trading partner's box are events that the trading partner has created themselves or received from their trading partner. Choreography diagrams help users to understand the interaction of trading partners as business processes that consume or produce EPCIS events are discussed, and as business and regulatory rules are applied. In addition, the diagrams make clear what information each trading partner has access to as the scenario progresses.

As documented in Part 5 of this guideline, each EPCIS event includes a defined set of data attributes. The following shorthand notation was developed to help communicate event data efficiently within diagrams. The shorthand notation uses an icon that represents the EPCIS event with the relevant information that is needed to understand the business and regulatory rules and constraints in the scenario.

Figure 18 provides the key to the shorthand notation used to represent EPCIS events in the choreography diagrams.

EPCIS NOTATION
NOTATION KEY

Participants

M = Manufacturer
W = Wholesaler
R = Repackager
D = Dispenser (Pharmacy, Hospital, Physician, Clinic, Dialysis Center)if needed , ie: W1, W2)
(use "()" if asserting other's data, ie: W(M))

$$C^M_a [TI] \, i$$

Indicates that this event took place under inference. That is, the items under consideration were not directly read, instead, the Business Step was initiated based on corroborating information.

Business Step

C = Commissioning
P = Packing
S = Shipping
R = Receiving
U = Unpacking
H = Holding
E = End of useful life

Disposition

a = active
d = destroyed
i = intransit
n = non-sellable
q = quarantined
r = recalled
s = stolen
rs= retail sold

Packaging

[TI] = Trade Item
[BU] = Bundle
[CA] = Case
[PA] = Pallet
[TO] = Tote

Figure 18: Shorthand Notation for Depicting EPCIS Events

ⓘ *The full lists of Business Steps and Dispositions can be found in the Core Business Vocabulary Standard.*

19. Forward Logistics Choreographies

The following diagrams provide examples of various scenarios that can take place as products move forward through the supply chain. This version of the guideline focuses on basic forward logistics supporting a one-up-one-down model. Future releases of this guideline will provide examples for additional forward logistics scenarios (e.g., drop shipments, repackaging, kitting, etc.), reverse logistics (e.g., recalls, returns, withdrawals, refusals, etc.) and exceptions (e.g., shortages, overages, data discrepancy, etc.).

19.1. Basic Forward Logistics

The following examples show how EPCIS events can be used to support basic forward logistics scenarios for product moving through the supply chain.

19.1.1. Ship a full case through the supply chain

The following examples depict a Manufacturer shipping a pallet of cases to a Wholesaler who then breaks the pallet down to its cases and ships a full case to the Dispenser warehouse.

In the Figure 19 scenario, each trading partner captures the correct EPCIS events; however, they only share the *Shipping* event with each other. (If necessary, each trading partner could collect the remaining events from their trading partners to assemble the full history of events for a particular trade item.)

BASIC FORWARD LOGISTICS
A HOMOGENEOUS CASE MOVES FROM MANUFACTURER TO WHOLESALER TO DISPENSER – SHARING ONLY SHIPPING INFORMATION (1-UP/1-DOWN)

Manufacturer

$C^{M}_{[TI]}$
$C^{M}_{[CA]}$
$C^{M}_{[PA]}$
$P^{M}_{[TI/CA]}$
$P^{M}_{[CA/PA]}$
$S^{M}_{[PA]}$

$S^{M}_{[PA]}$ →

Wholesaler

$R^{W}_{[PA]}$
$U^{W}_{[CA/PA]}$
$R^{W}_{[CA]}$
$S^{W}_{[CA]}$

$S^{W}_{[CA]}$ →

Dispenser

$R^{D}_{[CA]}$
$U^{D}_{[TI/CA]}$
$E^{D}_{[TI]}$

Figure 19: Ship full case through supply chain -- sharing *Shipping* events only

In the Figure 20 scenario, each trading partner captures the correct EPCIS events; however, they only share certain *pedigree events* to fulfill a one-up/one-down model. Note that the Wholesaler is shown to be asserting that the Manufacturer commissioned the trade item that the Wholesaler has shipped to the Dispenser.

BASIC FORWARD LOGISTICS

A HOMOGENEOUS CASE MOVES FROM MANUFACTURER TO WHOLESALER TO DISPENSER – SHARING PEDIGREE RELATED EVENTS (1-UP/1-DOWN)
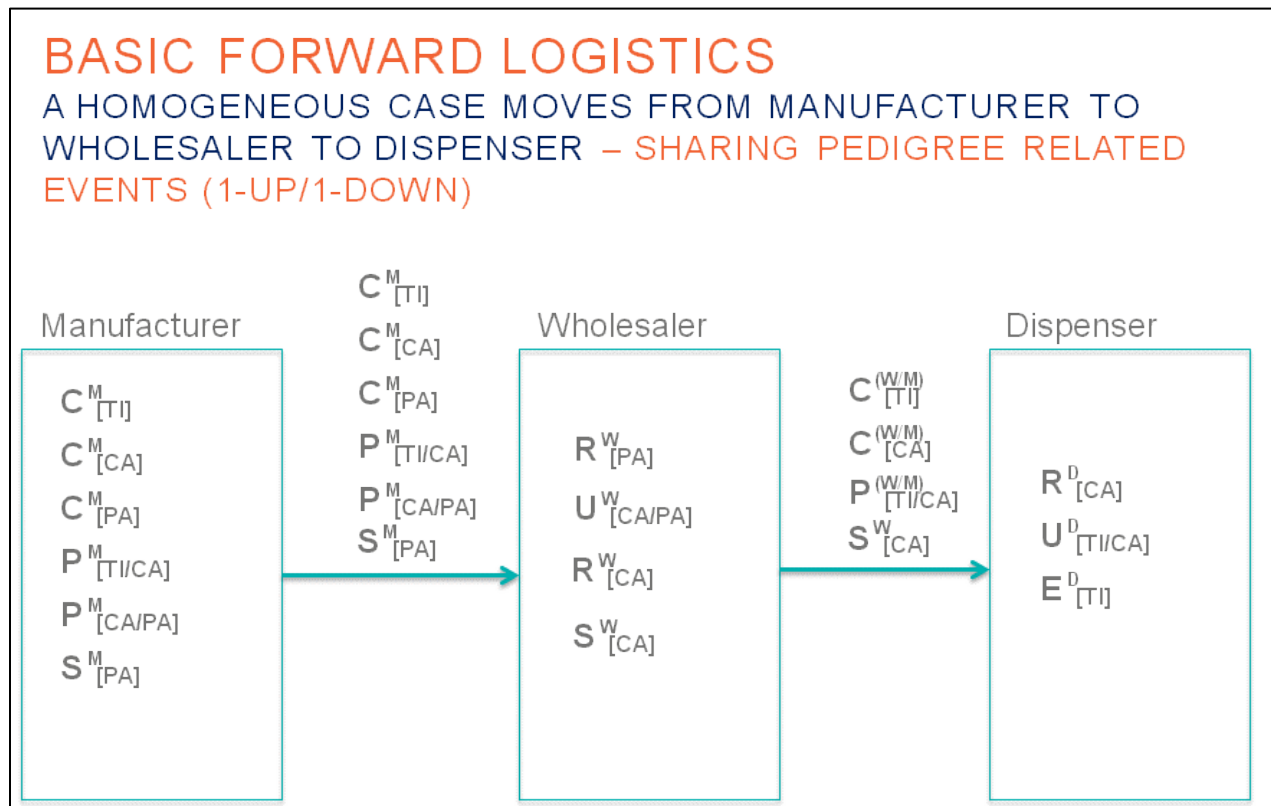
Figure 20: Ship full case through supply chain -- sharing *pedigree-related* events

19.1.2.   *Ship a pallet, break-down to trade items, pack and ship tote*

The following examples depict a Manufacturer shipping a pallet of cases to a Wholesaler who then breaks the pallet down into cases and then to the individual trade items. The Wholesaler then packs the trade items into a tote and ships the tote to the Dispenser.

In the Figure 21 scenario each trading partner captures the correct EPCIS events; however, they only share the *Shipping* event with each other. (If necessary, each trading partner could collect the remaining events from their trading partners to assemble the full history of events for a particular trade item.)
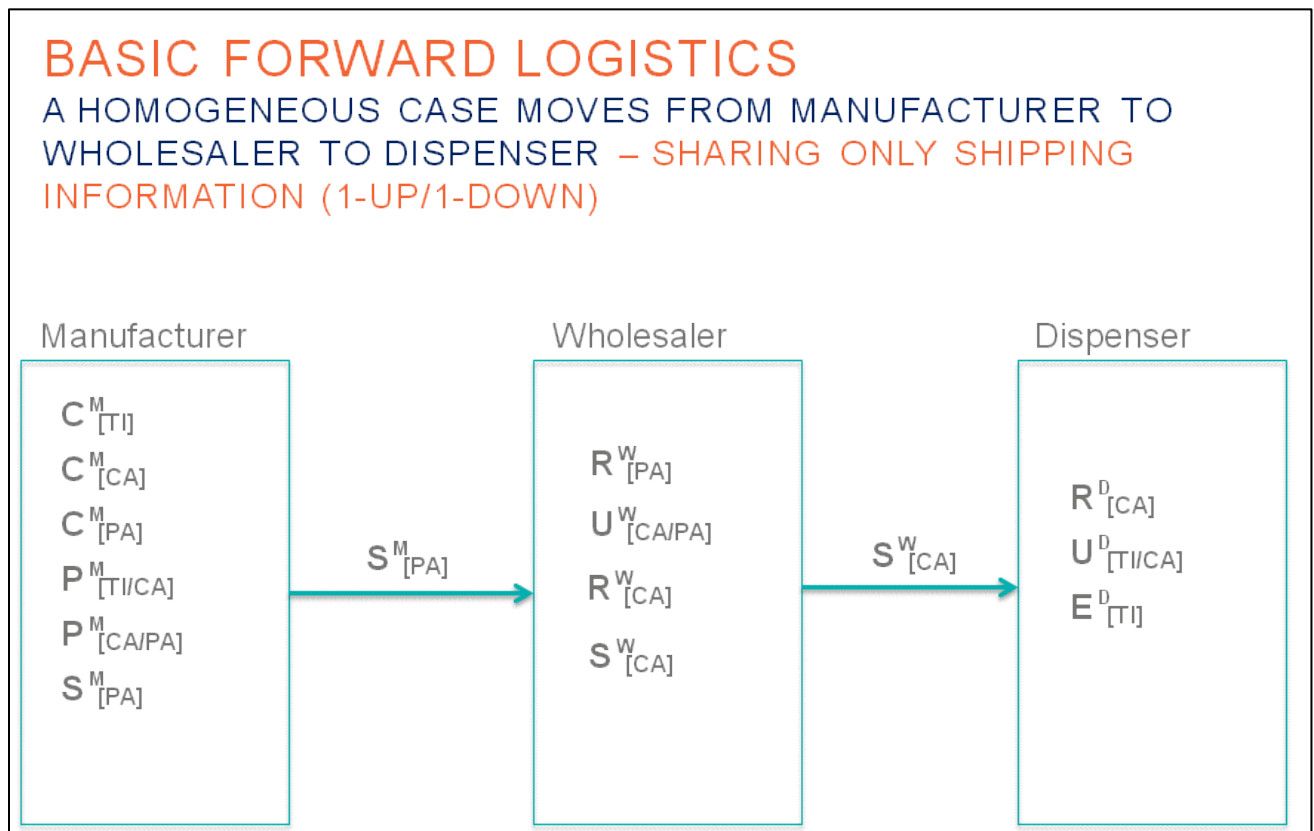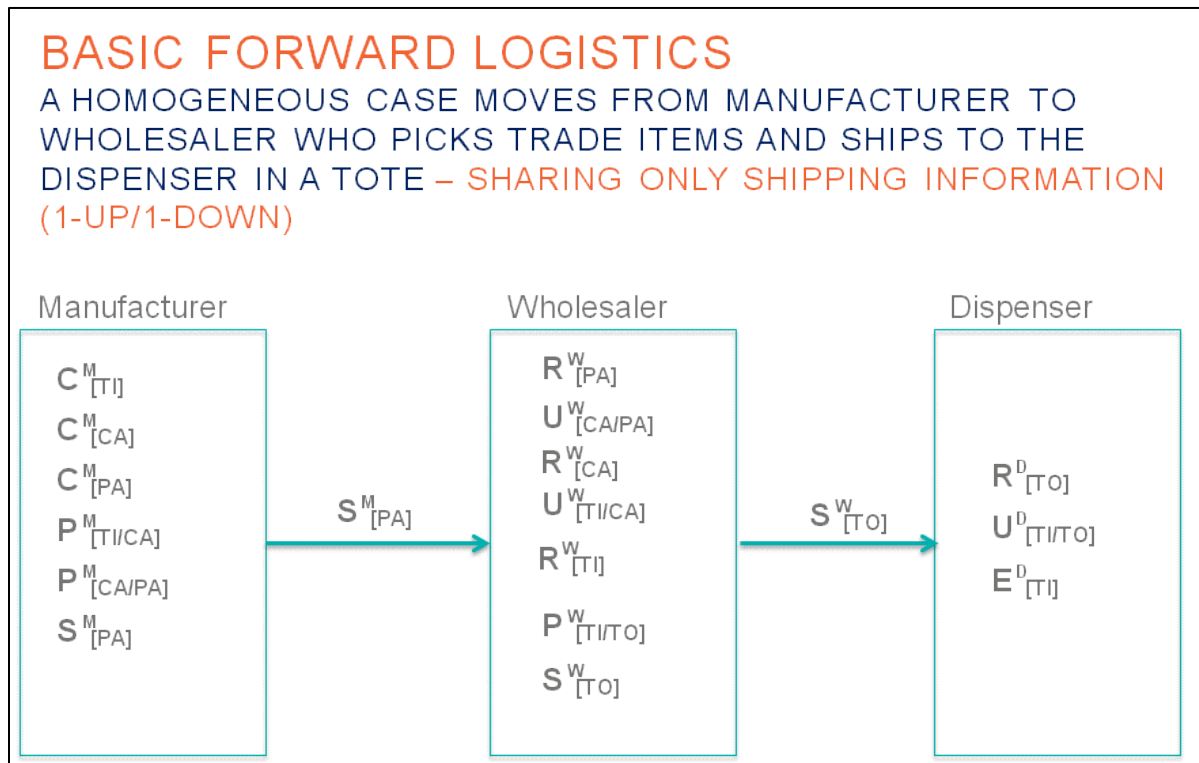

Figure 21: Ship pallet, break down to trade items, pack/ship totes -- sharing *Shipping* events only

In the Figure 22 scenario, each trading partner captures the correct EPCIS events; however, they only share certain *pedigree events* to fulfill a one-up/one-down model. Note that the Wholesaler is shown to be asserting that the Manufacturer commissioned the trade item that the Wholesaler has shipped to the Dispenser.

BASIC FORWARD LOGISTICS
A HOMOGENEOUS CASE MOVES FROM MANUFACTURER TO WHOLESALER WHO PICKS TRADE ITEMS AND SHIPS TO THE DISPENSER IN A TOTE – SHARING PEDIGREE RELATED INFORMATION (1-UP/1-DOWN)

Manufacturer

$C^M_{[TI]}$
$C^M_{[CA]}$
$C^M_{[PA]}$
$P^M_{[TI/CA]}$
$P^M_{[CA/PA]}$
$S^M_{[PA]}$

$C^M_{[TI]}$
$C^M_{[CA]}$
$C^M_{[PA]}$
$P^M_{[TI/CA]}$
$P^M_{[CA/PA]}$
$S^M_{[PA]}$

Wholesaler

$R^W_{[PA]}$
$U^W_{[CA/PA]}$
$R^W_{[CA]}$
$U^W_{[TI/CA]}$
$R^W_{[TI]}$

$P^W_{[TI/TO]}$
$S^W_{[TO]}$

$C^{(W/M)}_{[TI]}$
$P^W_{[TI/TO]}$
$S^W_{[TO]}$

Dispenser

$R^D_{[TO]}$
$U^D_{[TI/TO]}$
$E^D_{[TI]}$

Figure 22: Ship pallet, break down to trade items, pack/ship totes -- sharing *pedigree-related* events

Part 7: Exceptions Processing

This section was developed by the GS1 Healthcare US Secure Supply Chain Task Force as a means to start assessing how supply chain partners might further leverage the EPCIS standard to address exceptions within supply chain business processes that impact serialization and visibility.

20. Overview

Managing serialized products throughout the supply chain is an order of magnitude change for trading partners. As the industry prepares to manage serialized products while simultaneously tracking pedigree data for each and every saleable unit, it is likely that exceptions regarding pedigree-related data will occur early on. This section was developed by the GS1 Healthcare US Secure Supply Chain Task Force as a means to start assessing how supply chain partners might further leverage the EPCIS standard to address exceptions within supply chain business processes that impact serialization and visibility. It will be updated with additional insights into 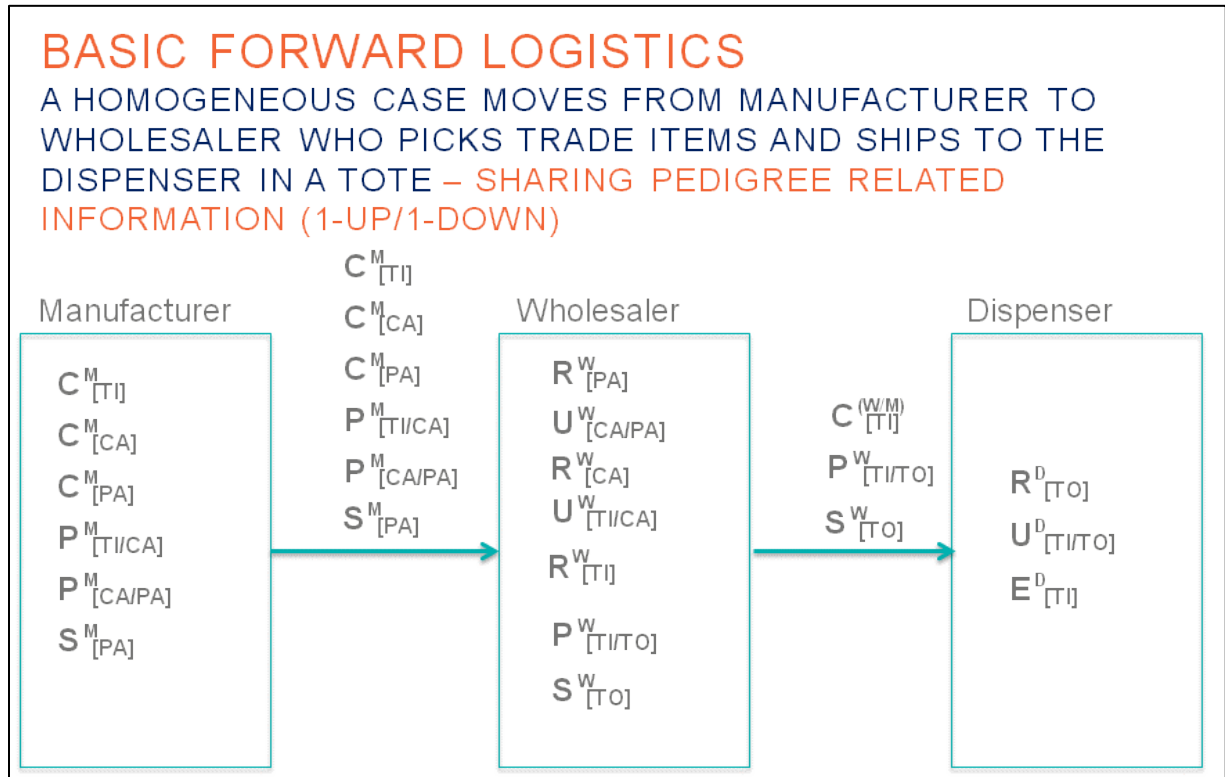exception processing from actual implementations, pilots and healthcare visibility programs. The primary goal is to address those exceptions that are likely to occur during the transition to serialized products.

This section identifies each known exception, defines the impact on the trading partners, and depicts how the trading partners could use EPCIS to notify each other that an exception had occurred. Later versions of this document may go further to define the full choreography of messages or EPCIS events needed to resolve the exceptions. While this section provides examples of exception processing using the EPCIS standard, it is recognized that there are other methods [e.g., Electronic Data Interchange (EDI), etc.] that may be used by individual trading partners.

It is anticipated that future versions of this guideline will provide detailed guidance on how companies may manage exceptions that can occur in a serialized, pedigreed world. The goal is to enable company systems to resolve exceptions with minimal human interaction by specifying EPCIS event choreographies that are aligned with the company's business rules and processes.

21. List of Exceptions

To date, the GS1 Healthcare US Secure Supply Chain Task Force has identified the following list of exceptions that could occur. As these exceptions and their resolutions are documented, it may be that some have the same root cause and will be consolidated. Likewise, as pilots and implementations continue to inform the content of this guideline, other exceptions may be uncovered and documented in this section in future releases.

Exception List:

1: Overage

2: Shortage

3: Pedigree Serial Number discrepancy

4: Pedigree Lot Number discrepancy

5: Pedigree Serial Number and Lot Number incorrect

6: Product inference problem

7: Quantity inference problem

8: Physical inventory overage

9: Physical inventory overage (concealed)

10: Physical inventory shortage (concealed)

11: Pedigree contains incorrect customer or location information

12: Pedigree contains incorrect product information

13: Pedigree contains incorrect reference number information

14: Pedigree (or EPCIS Ship Business Step) not received by customer

15: Undelivered shipment

16: Lost shipment

17: Received physical product from an unidentified sender

18: *Resolved (number maintained as placeholder)*

19: Could not read pedigree data due to security mismatch

20: Pedigree data not in correct format

21: Good product - damaged barcode or RFID

22: Damaged product - good barcode or RFID

23: Damaged product - damaged barcode or RFID

24: Damaged shipment

25: *Resolved – accounted for in other exceptions*

26: *Resolved – accounted for in other exceptions*

27: No parent – child aggregation

28: Pedigree data incomplete

29: Pedigree data has broken chain

30: Shipped product to wrong customer and pedigree data to correct customer

31: Customer refuses order

32: Unauthorized return

33: Shipment for Wholesaler "Y" arrives at Wholesaler "X"

Part 8: Appendices

22. Converting an 11-digit NDC to a 10-digit NDC

This section is provided for the benefit of billing system suppliers and users. Many National Drug Codes (NDCs) are displayed on drug packaging in a 10-digit format. Many billing systems require an 11-digit NDC number in a 5-4-2 format. The following table shows common 10-digit NDC formats indicated on packaging and the appropriate conversion to an 11-digit format for billing systems.

In the table below:

- The additional "0" in the 11-digit converted example is shown in **bold** and underlined.

- Hyphens have been inserted for visual clarity to illustrate the various formatting examples of NDCs. Do not use hyphens when entering the NDC in your claim.

10-Digit Format on Package	10-Digit Format Example	11-Digit Format	11-Digit Converted Example
4 - 4 - 2	0002-7597-01 Zyprexa 10mg vial	5 - 4 - 2	**0**0002-7597-01
5 - 3 - 2	50242-040-62 Xolair 150mg vial	5 - 4 - 2	50242-**0**040-62
5 - 4 - 1	60575-4112-1 Synagis 50mg vial	5 - 4 - 2	60575-4112-**0**1

Table O: Key to Assigning, Storing and Encoding GTINs

23. GS1 Standards

From an information management point of view, supply chain applications like pedigree and track and trace require all parties to systematically associate the physical flow of products with the flow of information about them. This is best attained by deploying a common business language within the framework of a comprehensive standards system. The GS1 System is such a system, providing a comprehensive platform for companies to identify products and other business entities, capture supply chain data, and share data with trading partners.

The GS1 System encompasses identification standards, data standards, automatic identification data capture (AIDC) standards, and data communication standards. Table 16 below summarizes some of the GS1 Standards that support pedigree and track and trace.

GS1 Standards Supporting Pedigree and Track & Trace			
Identification Standards	**Trade Items**	Global Trade Item Number (GTIN)	
	Locations & Trading Partners	Global Location Number (GLN)	
	Logistics Units	Serial Shipping Container Code (SSCC)	
	Individual Assets	Global Individual Asset Identifier (GIAI)	
	Returnable Assets	Global Returnable Asset Identifier (GRAI)	
AIDC Standards	**GS1 Barcodes**	GS1-128 GS1 DataMatrix RSS EAN/UPC ITF-14 Composite Component	
	GS1 EPC/RFID		
Data Standards	**Master Data:** Global Data Dictionary Item Business Messaging Standard Party Business Messaging Standard	**Transactional Data:** eCom/EDI	**Event Data:** EPCIS Schema EPCIS Core Business Vocabulary
Sharing & Communication Standards	**Master Data:** GDSN GLN Registry EPCIS Master Data	**Transactional Data:** AS2	**Event Data:** EPCIS Capture EPCIS Query Discovery Services

Table P: Overview of GS1 Standards to Support Pedigree and Track & Trace

24. Resource Links

- GS1 Healthcare US Website: http://www.gs1us.org/healthcare

- GS1 Healthcare US Tools and Resources: http://www.gs1us.org/hctools

- GLN Registry: http://www.gs1us.org/glnregistry

- *Healthcare Provider Tool Kit for GS1 Standards:* http://www.gs1us.org/hctoolkit

- *Healthcare Supplier Tool Kit for GS1 Standards:* http://www.gs1us.org/hctoolkit

- GS1 Healthcare US 2015 Readiness Program Report - Phase 1: Basic Forward Logistics: http://www.gs1us.org/hctools

- GS1 Healthcare US 2015 Readiness Program Report - Phase 2: Additional Forward Logistics: http://www.gs1us.org/hctools

- 2015 Readiness Pilot Reports: http://www.gs1us.org/hctools

- *The Practice of Inference in the U.S. Pharmaceutical Supply Chain:* http://www.gs1us.org/hctools

- *GS1 US Visibility Framework White Paper:* http://www.gs1us.org/visibility

- *Simplified Guide for U.S. Healthcare Barcode Scanner Acquisition Criteria* – Available on the GS1 US website at www.gs1us.org/hctools

- *Procedure for Responding to Troublesome Barcodes* – Available on the GS1 US website at www.gs1us.org/hctools

- *GS1 RFID Bar Code Interoperability Guideline -* Available in the Knowledge Center through the GS1 website at http://www.gs1.org/gsmp/kc/barcodes

25. Acronyms

AI	Application Identifier
CBV	Core Business Vocabulary
DPMS	Drug Pedigree Messaging Standard
EPC/RIFD	Electronic Product Code / Radio Frequency Identification
EPCIS	Electronic Product Code Information Services
XML	eXtensible Markup Language
GDSN	Global Data Synchronization Network
GLN	Global Location Number
GTIN	Global Trade Item Number
NDC	National Drug Code
RFID	Radio Frequency Identification
SSCC	Serial Shipping Container Code
SGLN	Serialized Global Location Number (GLN)
SGTIN	Serialized Global Trade Item Number (GTIN)
U.P.C.	Universal Product Code (U.P.C.)
URI	Uniform Resource Identifier
URN	Uniform Resource Name

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IAPMO

In this publication, the letters "U.P.C." are used solely as an abbreviation for the "Universal Product Code" which is a product identification system. They do not refer to the UPC, which is a federally registered certification mark of the International Association of Plumbing and Mechanical Officials (IAPMO) to certify compliance with a Uniform Plumbing Code as authorized by IAPMO.

Drop Shipments and the California Pedigree Law

Liz Gallenagh & John Howells
HDMA

California BOP Enforcement Committee
March 14, 2013

HDMA
Healthcare Distribution
Management Association

Overview

- Drop shipments defined in the statute
  - Legislature contemplated this type of transaction and the need to provide for an alternative to the "typical" pedigree requirements.
- The product goes directly from the manufacturer to the pharmacy
  - Exception: when there are exclusive distribution arrangements and a manufacturer designee is performing the drop shipment.
- One of the most secure transactions in the supply chain.

Statutory Definition

- 4163.1. (a) For purposes of Sections 4034 and 4163, "drop shipment" means a sale of a dangerous drug by the manufacturer of the dangerous drug whereby all of the following occur:

    (1) The pharmacy, or other person authorized by law to dispense or administer the drug, receives delivery of the dangerous drug directly from the manufacturer.

    (2) The wholesale distributor takes ownership of, but not physical possession of, the dangerous drug.

    (3) The wholesale distributor invoices the pharmacy or other person authorized by law to dispense or administer the drug in place of the manufacturer.

- (b) The board may develop regulations to establish an alternative process to convey the pedigree information required in Section 4034 for dangerous drugs that are sold by drop shipment.

Why Do Drop Shipments Occur?

- Type of product – predominantly Specialty Rx
  - Special handling, cold chain, etc.
  - Special administration/delivery to patient (IV, oncologics, etc.)
  - Out of stock/low stock.
- Emergencies.
- Critical Patient Need.

Drop Shipment
Manufacturer to Pharmacy

Manufacturer

Distributor
Invoice matching & exception processing

Pharmacy
Processing & reconciliation

Typical time is 3 – 7 days *

Data

Data

Product Shipment 1 – 2 days

The product is likely to be dispensed on the day of receipt or the next day.

CHDMA
Healthcare Distribution
Management Association

*exceptions can be up to 30 days

Manufacturer Designee Drop Ship

Manufacturer

Manufacturer Designee

Distributor
Invoice matching & exception processing

Pharmacy
Processing & reconciliation

Typical time is 3 – 7 days *

Data

Shipment

Data

Data
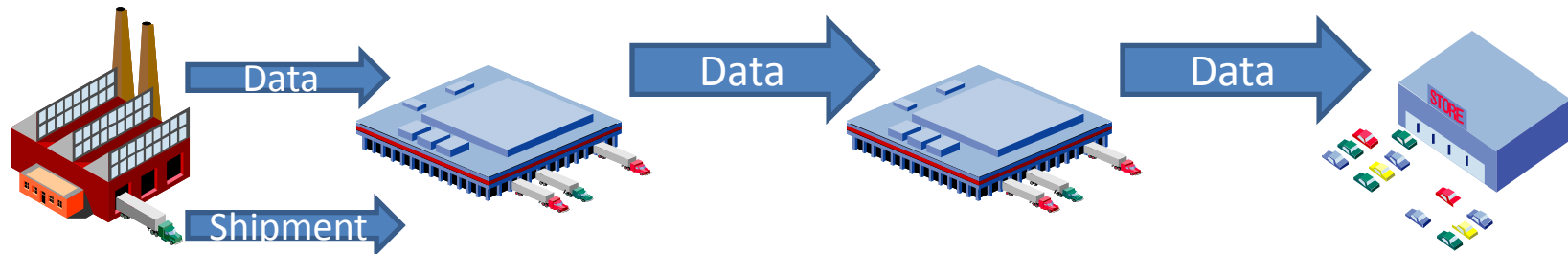
Product shipment takes 1 – 2 days

The product is likely to be dispensed on the day of receipt or the next day.

*exceptions can be up to 30 days

Reasons why drop shipments warrant consideration of an alternative

- In cases of critical patient need, do not want to delay dispensing of the product.
- In most drop ship cases, the drug has been administered before the wholesaler has been notified.
- This is an invoice / financial transaction. Invoice systems do not contain pedigree data.
- Pedigree and invoice systems are separate.
- Emergencies/exceptions can cause major delays in data processing.

Pedigree alternative for drop ship

- The financial "owner" of the product will not have custody of the product, and therefore, is not able to vouch for the pedigree associated with the product.

- In lieu of a pedigree, the manufacturer performing the drop shipment should indicate it is a drop shipment – either on the invoice (or via some other standard communication).

- The distributor in the center of the transaction (owns the product from a financial standpoint but does not have possession of the product) also indicates on its invoice that the product was drop shipped to the customer.

- Drop shipments by distributors also occur, particularly when there is an exclusive distributor relationship with the manufacturer or a product launch. The process for an exclusive distributor drop shipment should follow the same rules as a manufacturer drop shipment, as described above.

Questions?

Inference: Key to CA Pedigree Implementation

**California Board of Pharmacy
Enforcement Committee Meeting
September 11, 2012
Burlingame, CA**

CHDMA
Healthcare Distribution
Management Association

HDMA – Who We Represent

- Active members include 33 primary healthcare distributors – national, regional and specialty.

- HDMA's members offer value-added services that help ensure safe and timely delivery of nearly 9 million healthcare products to over 200,000 pharmacy and healthcare settings nationwide.

- Nearly 90 percent of all U.S. pharmaceutical sales go through HDMA distributors.

2

The Vital Link in a Sophisticated Supply Chain
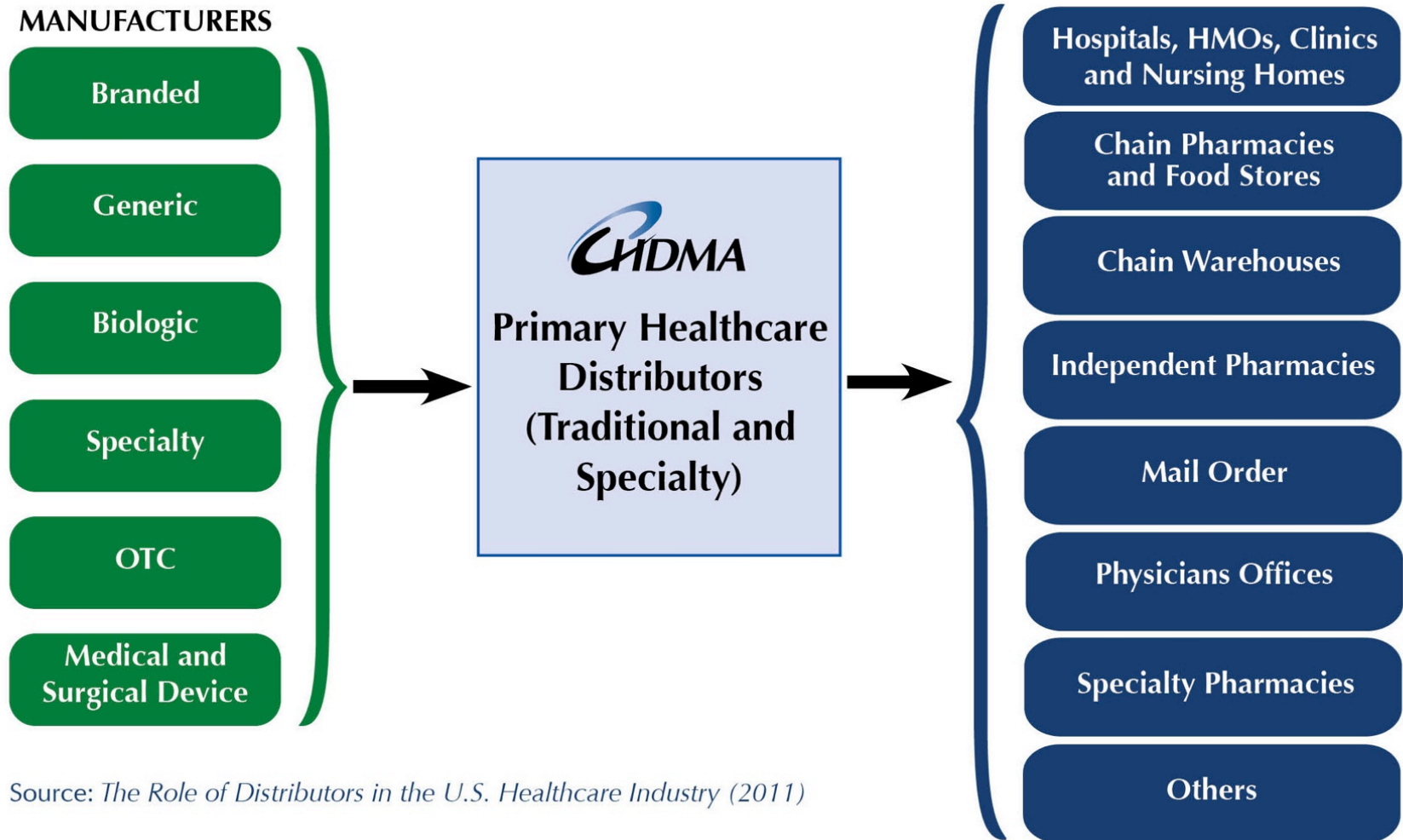
Source: *The Role of Distributors in the U.S. Healthcare Industry (2011)*

Healthcare Distributors

Typical companies inventory more than nearly 56,000 healthcare products from an average of 1,100 different manufacturers.

The average distribution center picks more than 95,000 items each day to fulfill nearly 2,000 customer orders.

Distributors deliver consolidated products on a next-day basis in low units of measure.

The typical distribution center serves nearly 1,200 customers and nearly 1,300 ship-to locations.

Source: 2011-2012 HDMA Factbook: The Facts, Figures & Trends in Healthcare (2011)

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HDMA in California

- California Customers: HDMA members deliver lifesaving medicines to approximately 32,000 customer locations in California.

- Jobs in California: HDMA member companies directly employ more than 6,600 California residents and contract for transportation and other services that support hundreds of additional jobs.

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HDMA in California

- **AmerisourceBergen Corporation**
  - Corona, Orange, Sacramento, San Bruno, Valencia

- **Cardinal Health, Inc**.
  - Elk Grove, Valencia

- **H. D. Smith**
  - Carson

- **McKesson Corporation**
  - City of Industry, Ontario, San Francisco, Santa Fe Springs, West Sacramento, Visalia

- **Valley Wholesale Drug Company**
  - Stockton

Inference - Background

- First emerged during development of the California pedigree law.

- The concept of unit level track-and-trace was based originally on the capabilities of RFID technologies.

- In 2007 or 2008, it became clear that manufacturers overwhelmingly believed that unit level serialization was more practical and economically feasible through the use of two dimensional (2D) data matrix bar codes. This was confirmed through HDMA's 2010 track and trace survey.

- 2D bar codes utilize "line of sight" technology, thus, an individual must scan each bar code in order to *directly* capture product information.

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Inbound Cases & Pallets

Inbound Cases & Pallets

Inbound Cases & Pallets

Case Level Bar Code Label

Distributor Volume

- On an average day, a typical HDMA member distribution center handles almost 2,000 customer orders, and picks (or processes) an average of 95,000 product units. Receipts come in from @ 1100+ mfrs.

- Scanning individual units on receipt is not practical or economically feasible.

- The Legislature understood the need for supply chain members to avoid having to unnecessarily open every single case of product

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Distributor Volume - Receiving

Distributor Volume - Receiving

Inference Example

- Wholesale Distributor XYZ orders and receives ten individual units in a sealed case (A) from the manufacturer of a product, along with a communication stating that these ten units were numbered 1 through 10 in case A. Because the manufacturer provided this information, and the same manufacturer sent Wholesale Distributor XYZ the case, XYZ can *infer* that what the manufacturer sent to it is what was stated by the manufacturer – without requiring Wholesale Distributor XYZ to open the case to confirm.

Handheld Scanner

Product Cases

Product Cases

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Open Product Case

Individual bottles in case

Major Changes in Operations

- The ability of HDMA primary distributor members to comply with the California law is heavily dependent upon manufacturer compliance beginning in January 2016.

- A future that includes serialized product, use of track-and-trace technologies, and electronic pedigree data exchange is one that has been contemplated, but we cannot yet fully understand or anticipate how such changes will require modifications to our members' operational and logistics functions.

Use of Inference When . . .

- Recipient places an order for product with the shipper, with whom the recipient has a business relationship; and

- A sealed homogenous (same lot, same product) case is sent by the shipper directly to the recipient; and

- The shipper and recipient have technology solutions to provide electronic business-to-business transactional security;

. . . all of these factors are present.

- And, the shipper sends – in advance of, or in conjunction with shipment – information about the items/contents of such case, including the items' serial numbers and pedigree information related to each specific case; and

- The recipient receives the case and the product information from the shipper.

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Inference is Necessary

- Allowing inference by distributors is necessary to help facilitate implementation of California's pedigree law.

- Allowance of inference is consistent with the spirit and the **intent** of the law – to employ technology and processes in the supply chain to permit electronic track-and-trace for the first time.

- **Without inference**, such technologies and processes will be difficult or impossible to successfully deploy.

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Safety, Efficiency and Access

- Inference will help to ensure that California providers and patients have continued access to life saving medicines.

- Inference will actually help ensure increased security of the supply chain by
  - Limiting open cases in a warehouse receiving area;
  - Limiting personnel handling items; and
  - Limiting opportunities for diversion, theft or contamination.

- Successful deployment of electronic track-and-trace technologies and processes is expected to decrease the risk of counterfeiting and diversion within the supply chain.

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Inference: Key to CA Implementation

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This is Big.

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Thank You

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